

Homeopathy: the scientific proofs of efficacy

Homeopathy: **the scientific proofs** **of efficacy**



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■ TABLE OF CONTENTS

PREFACE TO THE ENGLISH EDITION	7
PREFACE	9
INTRODUCTION	15
HOMEOPATHY: OVERVIEW OF BASIC RESEARC	17
HOMEOPATHY: OVERVIEW OF HUMAN CLINICAL TRIALS	29
■ <i>Historical review of the main publications</i>	29
SCIENTIFIC STUDIES THAT PROVE THE EFFICACY OF HOMEOPATHY	33
■ <i>Selected studies grouped by apparatus and disorder</i>	37
SYNOPTIC ANALYSIS OF 10 CLINICAL TRIALS	53
CONCLUSIONS	87

■ PREFACE TO THE ENGLISH EDITION

Any chemical agent that affects the processes of living is considered a drug. Duty of a physician is to study as many drugs as possible so that he can treat patients in the most appropriate way.

Everytime the physician seriously approaches the mechanisms of action of a given drug, he reaches for the limit of the “unknown”. For entities such as statins, or homeopathic dilutions, this limit is not very different. The only way to practically overcome this border, is to verify the effects of these entities. In this way, the real knowledge becomes the “effect in the contest”.

For this reason, I was not surprised when, as a clinical pharmacologist, I was asked to participate to an Advisory Board aimed to review a large body of clinical trials comparing some homeopathic therapies with placebo or allopathic medicaments. Immediately, I realized that, to compare therapies according to allopathic criteria, investigators have to sacrifice some of the potency and characteristics of non-allopathic remedies. These are based upon the assumption that every patient is a universe that needs a tailored therapy. The standardization, which is fundamental for the development of clinical trials, definitely limits the efficacy of homeopathy. Nevertheless, most of the trials that the Advisory Board analysed were conducted following an appropriate methodology and ended up with surprising results in favour of homeopathic remedies, both in terms of clinical activity and costs.

Furthermore, a high benefit risk ratio, based upon the ability to produce a desirable effect with minimal side effects, was achieved quite exclusively by the non-allopathic remedies.

Although these trials showed some outstanding results, I am afraid they will never overcome the prejudice.

I do not expect that detractors will modify their attitude because an Advisory Board has made a positive judgment pertaining to non-allopathic drugs. Moreover, I do not even expect that the entire homeopathy will gain credibility just because some medicaments have shown to be active. This is only an example on how it is possible to get together two different approaches. A good physician does not feel obliged to use one drug or the other, but will choose what he thinks is more suitable for the patient, and the clinical outcome will give him the most appropriate indications.

The pages of this compendium have been mainly constructed for those who believe that homeopathy and homotoxicology belong to the medical discipline.

These colleagues do not need any confirmation about the validity of these approaches, since they are supported by the daily evidence deriving from their patients. These pages have the duty to indicate that a more precise medical methodology may improve and extend the knowledge of homeopathy.

In conclusion, I hope that this compendium will be the first of many which will analyse all different aspects of these disciplines, and stimulate those physicians who are open-minded to review and discuss the new issues of the medical science. At the same time, since this document is coming from an Advisory Board of qualified scientists, it is also available for any Regulatory Agency who wants to be updated on some aspects of homeopathy.

I want to thank all the members of the Advisory Board who dedicate time and enthusiasm to the preparation of this compendium, particularly Prof. Leonello Milani and Dr. Alessandro Pizzoccaro who were collecting and selecting, with patience and sapience, the publications available in the medical literature.

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■ PREFACE

The specific purpose of this book is to test the “*paradoxical*” theory that homeopathic medicine has definite therapeutic effects, on the basis of scientific evidence.

In accordance with the standard pharmacological sense, it seems ridiculous to believe that a homeopathic medicine containing very low, sometimes undetectable concentrations of active constituents, could interact with a living organism and restore it to health.

Yet during the 200-year history of homeopathy, numerous studies have been conducted which appear to provide empirical confirmation of the therapeutic efficacy of homeopathic medicines.

Unfortunately, the vast majority of these studies used a special language and methodology which were incompatible with those of the academic and scientific world, thus relegating homeopathy to an inevitable long isolation.

We believe that this approach is unsuited to the purposes we aim to achieve with this volume.

Moreover, the therapeutic efficacy of homeopathic medicines may be confirmed by the fact that an increasing number of patients and doctors on every continent rely on homeopathy to solve their health problems.

A survey conducted by ISTAT (the Italian Statistics Institute) in September-December 1999 (“State of health and use of the National Health Service”) demonstrated that no less than five million Italians use homeopathic medicines, almost twice as many as in 1994, and even more people use this type of medicine in other European countries.

However, even these figures do not suffice for our purposes.

The Parliaments of numerous European and non-European countries have included homeopathic medicines in their legislation, and the health authorities have approved homeopathic pharmacopoeia, thus giving homeopathic medicines the status of drugs.

However, not even these official recognitions are sufficient for our approach.

Our specific aim is to establish whether it is possible to be certain, beyond all rea-

sonable doubt, that homeopathic medicines have therapeutic effects. We believe that the most objective method can only be based on scientific research, performed in strict compliance with its standard methodological criteria.

We also believe that if the efficacy of homeopathy can be proved, it must be communicated in the language used by the present-day scientific and academic community.

We have consequently performed a lengthy, detailed analysis of the extensive homeopathic literature and selected studies that comply strictly with scientific methodologies and criteria. Fortunately, the scientific quality of the studies performed in this field has considerably improved in the past 3-4 years, often reaching very high standards.

Our analysis concentrates mainly on these studies, in order to offer a comprehensive review of the state of the art in homeopathic high level research.

This analysis effort, performed under the supervision of an Advisory Committee, required the examination of a huge number of publications, and led to the production of an updated chart of homeopathic research.

The basic, significant findings of the selected studies are presented here, with all the bibliographical references required to allow further information from the source.

Our purpose is to offer readers basic information in a deliberately concise, concrete text which is solely aimed at presenting results based on rigorous research.

Finally, we have illustrated in greater detail ten particularly interesting studies on the efficacy of some homeopathic medicines vs allopathic medicines regularly used to treat the same disorders.

We consider these studies to be particularly significant because of their socio-medical implications.

We have not tackled here the various issues relating to “the epistemological basis of the experimental method in medicine”, “the extreme personalisation of homeopathic treatment”, “ethical doubts relating to pharmacological research”, “theoretical non-standardisation of the choice of homeopathic remedy”, “the absence of the usual dose-effect relationship”, “the explanation of the action mechanism of homeopathic remedies”, and so on.

Our aim is to reach a definite conclusion: do homeopathic medicines interact with living beings, and above all, can they restore health? As readers will see, we consider that these studies lead to the undeniable conclusion that homeopathic medicine possesses therapeutic efficacy.

At this point a number of consequences follow at various levels, in particular as regards the socio-medical, political and scientific aspects.

■ 1. Socio-medical aspects

Every doctor nowadays has an ethical duty to be familiar with homeopathic medicine which, it has been demonstrated, can be as useful to patients as “conventional” medicines in some situations. In addition, homeopathy offers some specific advantages:

- a. The cost is generally lower than that of the corresponding allopathic drug for the same disorder.
- b. By contrast with the high percentage of iatrogenic damage inevitably associated with the administration of allopathic medicines, homeopathic medicines have no side effects.
- c. As the remedy is harmless, huge control and monitoring structures do not need to be created.
- d. Homeopathic medicines manufacture procedures have no environmental impact.
- e. e. As homeopathic medicines are not patentable, manufacturers do not need to conduct expensive research in secret so as to be the first to develop new products. On the contrary, both old and new homeopathic findings are freely available to all. It may be precisely because of the non-patentability of homeopathic medicines that multinational drug manufacturers have never wished to enter this field.

■ 2. Political aspects

In view of these factors, it seems inevitable for political and parliamentary forces to introduce the following innovations into the legislation at an early date:

- a) Real freedom of treatment for doctors and patients, who are using non-conventional treatments to an increasing extent. The main stages in this process should involve:
 - introducing the concept of scientific pluralism into all possible spheres, including education legislation and the regulations of senior high schools and

universities; true science should not be dogmatic, but feature a variety of cognitive approaches, in our case involving trials with therapeutically active substances on healthy volunteers and patients

- abolishing discrimination against homeopathic medicines; their widespread availability should be promoted, they should be available on the National Health Service and under private health schemes, and they should be included in the national/regional Formulary. This would produce a reduction in per capita health spending on both drugs and hospitalisation.
- b) The presence of experts in non-conventional medicine in all organisations responsible for evaluations and marketing authorisations, such as the Single Drug Commission and the Senior Health Council.
 - c) The appropriation of sufficient funds by the National Research Council and similar organisations in favour of non-conventional medicine. Basic pharmacological research would thus be promoted, and especially essential studies on the clinical efficacy of the various therapeutic approaches used by non-conventional medicine, to define their fields of use and action.
 - d) Teaching of non-conventional medical subjects in university medicine and pharmacy faculties. The government should safeguard and guarantee adequate professional training in the interests of all users.

We are confident that these innovations will soon be introduced, because the new way of perceiving ourselves and interpreting illness and wellness is already firmly rooted in society. If the political world does not take this action, it will demonstrate that it is unaware of these present-day aspirations, triggering pointless tension and slowing the natural development of society.

■ 3. Scientific aspects

New and fascinating research frontiers have opened up; if an active constituent infinitesimally diluted (in accordance with the peculiar homeopathic procedure) has a therapeutic action, it is possible that the structure of water, the main solvent used, conceals unknown properties, which need to be studied as they may lead to some interesting, important discoveries.

Some promising studies have been conducted on these lines by Italian physicists Preparata and Del Giudice (*Del Giudice E., Preparata G. -1995: Coherent dynamics in water as a possible explanation of biological membranes formation. J. Biol. Phys. 20:105-116*) and more recently by Geckeler and Sama (*Geckeler C., Sama S.*

– *Chemical Communication 2001: 2224; Coughan A. – New Scientist, Nov. 2001*). At the same time, a possible rational explanation for the action mechanism of homeopathically diluted drugs is supplied by immunoregulation via “bystander suppression” (*H. Heine, M. Schmolz – Immunoregulation via “bystander suppression” needs minute amounts of substances – a basis for homeopathic therapy? – Med Hypotheses, 2000 Mar; 54(3):392-3*).

Rapid increases in the number of clinical trials performed, comprising open clinical trials and controlled clinical trials versus placebo or reference allopathic drug, are likely, because the methodological bases for research in the homeopathic field have now been defined in accordance with the criteria used by the international scientific community, and because growing interest in this field by patients, doctors, researchers and public institutions, all over the world, will inevitably lead to a plethora of research.

In this preface we have mentioned numerous aspects associated with the field of homeopathy, each of which deserves to be developed in greater detail, and we propose to do so in the near future.

The main purpose of the work condensed in this volume, however, was to establish whether definite proof exists that homeopathic medicines possess therapeutic efficacy, and we believe that this objective has been achieved beyond all reasonable doubt.

Alessandro Pizzoccaro
Chairman of Guna

■ INTRODUCTION

The “homeopathy phenomenon” has exploded all over the world; from an alternative medicine for a select few it has become the alternative medicine for millions of human beings (*Hlatry M.A. – Patients’ preferences and clinical guidelines. JAMA, 1995; 273:1219-20*).

Many authors writing in international non-homeopathic medical journals have investigated the reasons why homeopathy is so successful (*Campion, 1993; Sutherland, 1994; Vincent, 1996; Astin, 1998; Horton, 1998*) (see Bibliography at the end of this chapter).

Leaving aside criticisms which are biased and prejudiced rather than objective and scientific, and “philosophical” rather than rational, the answer is simple and obvious: homeopathy works. However, it is necessary to investigate the types of illness in which its therapeutic activity works best, and explore its limitations and boundaries.

“... science is not an opinion. In the scientific field, things are black and white: either a treatment works or it doesn’t, and if it works, it must be possible to demonstrate it. Once a result has been obtained with reliable experiments, you have to abide by it” (Prof. U. Veronesi – answer to a question published in Oggi magazine: 5-11-2001).

We are pleased to see that the Italian Health Minister, Prof. G. Sirchia, has announced that *“homeopathic medicines will become available on the National Health Service if their efficacy is proved”* (*Corriere della Sera; 7-2-2002*).

Numerous rigorous “*in vivo*” and “*in vitro*” tests (basic research) and controlled clinical trials have already been conducted using the same protocols as are currently required for any medical trial, so it is perfectly correct to speak of the “*homeopathic verum*”.

The world of homeopathic research is moving in the direction of investigating its rational, explicable, demonstrable, reproducible aspects and neglecting the more controversial and doubtful aspects. The purpose of this publication is to review the extensive literature available, and draw the reader’s attention to studies that comply with the strictest scientific methodologies.

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HOMEOPATHY: OVERVIEW OF BASIC RESEARCH

We have analysed the numerous *in vitro* and *in vivo* pharmacological studies which have been conducted on the activity of homeopathic medicines, both unitary (having a single active constituent) and complex (having a number of active constituents).

Of the hundreds of studies examined, we have selected **65** publications: **38** relating to unitary and **27** to compound homeopathic medicines, In each case the original bibliographical source is cited, together with the title in English (translation or original), where available.

The purpose of this volume is to analyse in particular some of the most significant publications relating to human clinical trials of homeopathic medicines versus placebo and homeopathic medicines versus conventional medicines.

We also consider it interesting to mention the **most significant** *in vivo* and *in vitro* studies designed to establish the efficacy of homeopathic medicines, because basic research is crucial to the advance of medical and biological knowledge, and is the necessary prelude to human clinical trials.

STUDIES OF THE ACTIVITY OF HOMEOPATHIC MEDICINES

SELECTED PUBLICATIONS

In ascending chronological order

ORIGINAL/TRANSLATED TITLE	AUTHOR(S)	PUBLICATION	ACTIVITY	STUDY
Inhibition of lymphoblast transformation test (LTT) in phytohaemagglutinin (PHA) with <i>Phytolacca americana</i> in homeopathic dilution	Colas H., Aubin M., Picard P., Lebecq J.C.	<i>Ann. Homéopat. Fr.</i> , 1975, 6: 1-11.	Inhibitory	Lymphoblast transformation
Inquiry into the limits of biological effects of chemical compounds in tissue culture. I. Low dose effects of mercure chloride	Mansvelt J.D., van Amons E.	<i>Z. Naturforschung</i> , 1975, 30: 643-649.	Inhibitory	Lymphocyte growth
The effects of <i>Belladonna</i> and <i>Ferrum phosphoricum</i> on the chemoluminescence of human poly-morphonuclear neutrophils	Poitevin B., Aubin M., Royer J.F.	<i>Ann. Homéop. Fr.</i> , 1983, 3: 5-12.	Inhibitory	Radical release
Effect of <i>aconitum</i> and <i>veratrum</i> on the isolated perfused heart of the common eel (<i>Anguilla anguilla</i>)	Pennec J.P., Aubin M.	<i>Comp. Biochem. Physiol.</i> , 1984, 77c: 367-369.	Protective	Aconitine toxicity
Elements of homeopathic pharmacology	Aubin M.	<i>Homéopathie Franç.</i> , 1984, 72: 231- 235.	Protective	Aconitine toxicity
The effect of homeopathic preparations on the phagocyte activity of granulocytes. In vitro tests and double-blind controlled trials	Wagner H., Jurcic K., Doenicke A., Rosenhuber E., Behrens N.	<i>Arzneim. Forsch./Drug Res.</i> , 1986, 36: 1424-1425.	Stimulant	Phagocytosis
Approach to quantitative analysis of the effect of <i>Apis mellifica</i> on the degranulation of human basophils cultivated in vitro	Poitevin B., Aubin M., Benveniste J.	<i>Innov. Tech. Biol. Med.</i> , 1986, 7: 64-68.	Inhibitory	Basophil degranulation
In vitro stimulation of human granulocytes and lymphocytes by pico- and femtogram quantities of cytostatic agents	Wagner H., Kreher B., Jurcic K.	<i>Arzneim. Forsch./Drug Res.</i> , 1988, 38: 273-275.	Stimulant	Lymphocyte growth
Human basophil degranulation triggered by very dilute antiserum against IgE	Davenas E., Beauvais F., Amara J., Robinson M., Miadonna A., Tedeschi A., Pomeranz B., Fortner P., Belon P., Sainte-Laudy J., Poitevin B., Benveniste J.	<i>Nature</i> , 1988, 333: 816-818.	Stimulant	Basophils

ORIGINAL/TRANSLATED TITLE	AUTHOR(S)	PUBLICATION	ACTIVITY	TRIAL
In vitro immunological degranulation of human basophils is modulated by lung histamine and <i>Apis mellifica</i>	Poitevin B., Davenas E., Benveniste J.	<i>Brit. J. Clin. Pharmacol.</i> , 1988, 25: 439-444.	Inhibitory	Basophil degranulation
Cytotoxic agents as immunomodulators	Wagner H., Kreher B.	<i>Proc. of the 3rd GIRI meeting</i> , Paris, 1989, 31-	Stimulant	Lymphocyte growth
Contributions of fundamental research in homeopathy	Boiron J., Belon P.	<i>Berl. J. Res. Hom.</i> , 1990, 1: 34-35.	Inhibitory	Basophil degranulation
Synergism of action between indoleacetic acid (IAA) and highly diluted solutions of CaCO ₃ on the growth of oat coleoptiles	Bomroni C.	<i>Berl. J. Res. Hom.</i> , 1991, 1 (4/5): 275-278.	Stimulant	Growth of plant cells
Study of the action of Hahnemannian dilutions of mercury chloride on the mitotic index in animal cell cultures.	Boiron J., Abecassis J., Cotte J., Bernard A.M.	<i>Ann. Homéop. Fr.</i> , 1991, 23: 43-49.	Protective	Hg toxicity
Dual effects of formylpeptides on the adhesion of endotoxin-primed human neutrophils	Bellavite P., Chirumbolo S., Lippi G., Andrioli G., Bonazzi L., Ferro I.	<i>Cell. Biochem. Funct.</i> , 1993, 11: 231-239.	Inhibitory	Cell adhesion (bact. pept. 10 ⁻⁸ -10 ⁹)
Effects of homeopathic preparations of organic acids and of minerals on the oxidative metabolism of human neutrophils	Chirumbolo S., Signorini A., Bianchi I., Lippi G., Bellavite P.	<i>Br. Hom. J.</i> , 1993, 82: 227-244.	Inhibitory	Leucocyte activation (metabolism)
Platelets/endothelial cells interactions in presence of acetylsalicylic acid at ultra low dose	Doutremepuich C., Lalanne M.C., Ramboer I., Sertillanges M.N., De Seze O.	<i>Omeomed 92 (C. Bomroni, ed.)</i> , 1993, Editrice Compositori, Bologna: 109-115.	Inhibitory	Prostacyclin release
Effect of high dilutions of epidermal growth factor (EGF) on <i>in vitro</i> proliferation of keratinocyte and fibroblast cell lines	Fougeray S., Moubry K., Vallot N., Bastide M.	<i>Br. Hom. J.</i> , 1993, 82: 124-125.	Inhibitory	Growth of keratinocytes
Effects of different homeopathic potencies of Lachesis on lymphocyte cultures obtained from rabbit blood	Enbergs H., Arndt G.	<i>Biol. Tier.</i> , 1993, 4.	Stimulant	Mitotic and immunostimulating activity (bact. pept 10 ⁻⁵ -10 ⁶)
The effect of homeopathic potencies of house dust mite on the migration of house-dust-sensitive human leukocytes	Gibson S.L., Gibson R.G.	<i>Complement. Ther. Med.</i> , 1996, 4: 169-171.	Stimulant	Leucocyte chemotaxis
The effects of <i>Nux vomica</i> Homaccord and <i>Atropinum comp.</i> on intestinal activity <i>in vitro</i>	Kanui T.I., Enbergs H.	<i>Biol. Tier.</i> , 1996/1, 43-47.	Stimulant	Contraction of intestinal muscles

ORIGINAL/TRANSLATED TITLE	AUTHOR(S)	PUBLICATION	ACTIVITY	TRIAL
Application of flow cytometry to the analysis of the immunosuppressive effect of histamine dilutions on human basophil action: effect of cimetidine	Sainte-Laudy J., Belon P.	<i>Inflamm. Res.</i> , 1997, 46: S27-S28.	Inhibitory	Basophil degranulation
Effects of Podophillum pellatum compounds in various preparations and dilutions on human neutrophil functions in vitro	Chirumbolo S., Conforti A., Lussignoli S., Metelmann H. et Al.	<i>Br. Hom. J.</i> , 1997; 86-16.	Inhibitory	Release of superoxides
<i>In vivo</i> and <i>in vitro</i> studies on the efficiency of potentized and non-potentized substances	Harisch G., Dittmann J.	<i>BT</i> , 1997, 2; 40-46.	Difference between potentised and non-potentised substances	<i>In vivo</i> and <i>in vitro</i> study; basic research
Experiments with the effects of Ubichinon-Injeel and strong Ubichinon-Injeel on an acellular system	Harisch G., Dittmann J.	<i>BM</i> , 1997, 3; 99-104.	Different effects of associations of various potencies and individual potencies	<i>In vitro</i> study; basic research
Efficacy of the homeopathic drugs Suis and Arnica comp.-Heel® on lymphocyte and phagocyte activity	Enbergs H.	<i>BM</i> , 1998, 1; 3-11.	Effect of organotherapeutics and Arnica comp. - Heel® on immune system cells	<i>In vitro</i> study; basic research
Influence of dilutions and potencies of cAMP on different enzymatic systems	Harisch G., Dittmann J.	<i>BM</i> , 1998, 2; 55-62.	Effects of dilutions and potencies of cAMP on some enzymatic activities	<i>In vitro</i> study; basic research
Studies of the principles of homeopathy; the changeover from <i>in vivo</i> to <i>in vitro</i> experimental research	Harisch G., Dittmann J.	<i>BM</i> , 1998, 3; 98-103.	Potentised and non-potentised dilutions are equally effective, but have different actions	Basic research
Determination of the activity of acid phosphatase with cAMP at various potencies	Harisch G., Dittmann J.	<i>BM</i> , 1999, 1; 4-8.	Different effects on enzymatic activity	<i>In vitro</i> study; basic research
Contribution to study of the efficacy of homeopathic potencies of phosphorus	Gomez J.C.	<i>BT</i> , 1999, 2; 52-57	Effect of different potencies of phosphorus	Tests on guinea pigs
Determination of the activity of acid phosphatase in the presence of Ubichinon comp.	Harisch G., Dittmann J.	<i>BM</i> , 1999, 4; 188-194.	Effect of enzymatic activity of homeopathic medicine	Basic research
Biochemical efficacy of homeopathic and electronic preparations of D8 potassium cyanate	Dittmann J., Kanapin H., Harisch G.	<i>FKM</i> , 1999, 6; 15-18.	Homeopathic potentisation is more effective than electronic potentisation	Basic research

ORIGINAL/TRANSLATED TITLE	AUTHOR(S)	PUBLICATION	ACTIVITY	TRIAL
Osteoporosis in vitro in rat tibia-derived osteoblasts is promoted by the homeopathic preparation, FMS Calciumfluor	Palermo C., Filanti C., Poggi S., Manduca P.	<i>Cell Biol Int</i> , 1999, 23(1): 31-40.	Stimulant	Osteogenesis (trial with compound drug)
Thin-layer chromatography (TLC) of homeopathic active constituents	Schmolz M.	<i>BM</i> , 1999, 5; 248-250.	Constituents of Arnica comp.-Heel® ointment: electrophoresis accelerates their skin penetration.	Basic research
			Effect of homeopathic constituents on enzymatic activity.	Basic research
Efficacy of a potentised homeopathic drug in reducing cytotoxic effects produced by arsenic trioxide in mice	Datta S., Mallick P., Bukhsh A.R.	<i>Complement Ther Med</i> , 1999 Jan; 7 (8): 62-75 (a).	Protective	Arsenic trioxide toxicity
Efficacy of a potentised homeopathic drug in reducing cytotoxic effects produced by arsenic trioxide in mice	Datta S., Mallick P., Bukhsh A.R.	<i>Complement Ther Med</i> , 1999 Sep; 7 (3): 156-63 (b).	Protective	Arsenic trioxide toxicity
Non-cytotoxic antiviral action of a homeopathic drug	Heine H.	<i>Ärzteitschrift für Naturheilverfahren</i> , 2000; 41: 542-7.	Stimulant	γ interferon synthesis
Efficacy of a potentised homeopathic drug in reducing cytotoxic effects produced by arsenic trioxide in mice	Kundu S.N., Mitra K., Khuda Bukhsh A.R.	<i>Complement Ther Med</i> , 2000 Sep; 1 (3): 157-65.	Protective	Arsenic toxicity
Stimulatory effect of some plant extracts used in homeopathy on the phagocytosis induced chemiluminescence of polymorphonuclear leukocytes	Crocnan D., Greabu M., Olinescu R.	<i>Rocz Akad Med Biochemist</i> , 2000; 45: 246-254.	Stimulant	Phagocytosis
Difference between the efficacy of single potencies and chords	Dittmann J., Harisch G.	<i>BM</i> , 2000, 1; 18-23.	Potency chords are more effective than single potencies	Basic research
Influence of some homeopathic drugs on the catalytic activity of uricase, acid phosphatase and the cytosol glutathion-S-transferase	Dittmann J., Kanapin H., Harisch G.	<i>BM</i> , 2000, 3; 125-131	Effect of D8 potencies on three different enzymatic systems	Basic research
Influence of some homeopathic drugs on the catalytic activity of cAMP-dependent protein kinases	Dittmann J., Kanapin H., Harisch G.	<i>BM</i> , 2000, 6; 289-296.	Effect of different potencies of 5 substances on enzymatic activity	Basic research

ORIGINAL/TRANSLATED TITLE	AUTHOR(S)	PUBLICATION	ACTIVITY	TRIAL
Neuroprotection from glutamate toxicity with ultra-low dose glutamate	Jonas W., Lin Y., Zortella F.	<i>Neuroreport</i> , 2001 Feb 92; 12 (2): 335-9.	Protective	Glutamate toxicity

KEY: BT = Biomedical Therapy
 BM = Biologische Medizin
 FKM = Forschung Komplementär Medizin

STUDIES OF BYSTANDER REACTION

SELECTED PUBLICATIONS

In ascending chronological order

ORIGINAL/TRANSLATED TITLE	AUTHOR(S)	PUBLICATION	ACTIVITY	TRIAL
Induction of bystander reaction with homeopathic remedies of plant origin	Heine H., Schmolz M.	<i>BM</i> , 1998, 1; 12-14.	Atropa belladonna, Bellis perennis and Conium maculatum	Basic research
The action mechanism of some homeopathic drugs in accordance with homotoxicology	Heine H.	<i>BM</i> , 1999, 1; 19-23.	Effect of some homeopathic substances on TGF- β	Basic research
Homotoxicological homeopathic remedies which modulate TGF- β synthesis in human blood cultures	Schmolz M., Heine H.	<i>BM</i> , 2001, 2; 61-65.	20 substances in 5 potencies were tested to establish their effects on TGF- β synthesis.	Basic research

KEY: BM = Biologische Medizin 7.0

STUDIES OF THE HOMEOPATHIC DRUG ARNICA COMP.-HEEL®

SELECTED PUBLICATIONS

In ascending chronological order

ORIGINAL/TRANSLATED TITLE	AUTHOR(S)	PUBLICATION	ACTIVITY	TRIAL
Experimental study of the anti-inflammatory activity of homeopathic drugs	Conforti A., Bertani B., Metelmann H., Chirumbolo S., Lussignoli S., Bellavite P.	<i>BT</i> , 1997, 1; 28-31.	Effect on superoxide anion production and platelet adhesion	<i>In vivo</i> and <i>in vitro</i> experiments; basic research
Efficacy of the homeopathic drugs Suis and Arnica comp.-Heel® on lymphocyte and phagocyte activity	Enbergs H.	<i>BM</i> , 1998, 1; 3-11.	Effect of Arnica comp.-Heel® and organotherapeutics on immunocompetent cells	Basic research
Induction of bystander reaction with plant extracts	Heine H, Schmolz M.	<i>BM</i> , 1998, 1; 12-14.	Atropa belladonna, Bellis perennis and Conium maculatum	Basic research
The effects of homotoxicological drugs on acute and chronic inflammations	Conforti A., Bertani B., Lussignoli S., Bellavite P.	<i>BM</i> , 1998, 2; 63-66.	Effect on superoxide anion production and platelet adhesion	<i>In vivo</i> and <i>in vitro</i> study; basic research
The effects of Arnica comp.-Heel® on inflammation induced in rats	Lussignoli S., Bertani B., Metelmann H., Bellavite P., Conforti A.	<i>CTM</i> , 1999, 7; 225-230.	Effect of Arnica comp.-Heel® and its individual constituents on oedema induced in the rat	<i>In vivo</i> study (rat); basic research

KEY: BT = Biomedical Therapy
 BM = Biologische Medizin
 CTM = Complementary Therapies in Medicine

STUDIES OF THE HOMEOPATHIC MEDICINE ZEEL® T

SELECTED PUBLICATIONS

In ascending chronological order

ORIGINAL/TRANSLATED TITLE	AUTHOR(S)	PUBLICATION	ACTIVITY	TRIAL
Incubation of drugs for new cartilage synthesis	Weh L., Fröschle J.	<i>EO</i> , 1982, 4; 303-308.	Effect on new cartilage synthesis	Basic research
The efficacy of Zeel T verified by new in vitro test models	Orlandini A., Rossi M., Setti M., Cantaluppi G.	<i>La Medicina Biologica</i> , 1996, 3; 26-35.	Chondroprotective effect	<i>In vitro</i> study; basic research
In vitro inhibition of leucocyte elastase with Zeel®T	Stancikova M.	<i>BM</i> , 1999, 2; 83-84.	Inhibition of leucocyte elastase	Basic research
The effects of Zeel® T on experimentally induced osteoarthritis	Stancikova M., Bely M., Svik K., Metelmann H., Schmolz M., Istok R., Fano R.	<i>Rheumatologia</i> , 1999, 3; 101-108.	Effects on experimental osteoarthritis	Standard research on animals; basic research
Multiphase mineralisation associated with cartilage disease and pharmacologically induced partial reversibility	Rossi M.	<i>La Medicina Biologica</i> , 2002, 2; 21-28.	Multiphase mineralisation	Basic research

KEY: EO = Extracta Orthopaedica
 BM = Biologische Medizin

STUDIES OF THE HOMEOPATHIC MEDICINE EUPHORBIIUM COMPOSITUM® S

SELECTED PUBLICATIONS

In ascending chronological order

ORIGINAL/TRANSLATED TITLE	AUTHOR(S)	PUBLICATION	ACTIVITY	TRIAL
Modulation of cytosine synthesis in human leucocytes by individual constituents of Euphorbium comp.-S	Schmolz M., Metelmann H.	<i>BM</i> , 1998, 4; 155-158.	Effect on immunocompetent human cells	<i>In vitro</i> study; basic research
The antiviral effect of Euphorbium compositum S	Metelmann H., Glatthaar-Saalmüller B.	<i>BM</i> , 1999, 3; 142-146.	Inhibition of viral replication (3 viruses)	<i>In vitro</i> study
The influence of a homotoxicological drug on the human immune system	Schmolz M., Weiser S.	<i>BM</i> , 2001, 3; 132-135.	Influence on immunocomponent cytokine levels	Basic research; determination of blood TGF- β and IL-6 in 20 healthy volunteers (<i>in vivo</i>)
The antiviral action of Euphorbium compositum and its constituents	Glatthaar-Saalmüller B., Fallier-Becker P.	<i>FKKN</i> , 2001, 4; 207-212.	Inhibition of virus proliferation (4 viruses)	<i>In vitro</i> study

KEY: BM = Biologische Medizin
 FKKN = Forsch Komplementärmed Klass Naturheilkd

OTHER STUDIES OF COMPLEX HOMEOPATHIC MEDICINES

SELECTED PUBLICATIONS

In ascending chronological order

DRUG	ORIGINAL/TRANSLATED	AUTHOR(S)	PUBLICATION	ACTIVITY	TRIAL
Engystol® + Aconitum-Heel®	Immune stimulation of some homeopathic drugs	Wagner H.	<i>BM</i> , 1985, 2; 399-407.	Effect on phagocyte activity	Basic research
Engystol® + Aconitum-Heel®	Influence of homeopathic drugs on granulocyte phagocytosis	Wagner H., Jurcic K.	<i>Arzn. Forsch.</i> , 1986, 9; 1421-1425.	Effect on phagocyte activity	<i>In vitro</i> study; basic research
Cocculus-Heel®	Induction of bystander reaction	Heine H., Schmolz M.	<i>BM</i> , 1998, 1; 12-14.	Atropa belladonna, Bellis perennis, Conium maculatum	Basic research
Engystol®S	The immunomodulating effect of Engystol® S on some human leucocyte isolate activities	Fimiani VM., Cavallaro J.	<i>II</i> , 2000, 1; 103-15.	Lymphokine secretion	<i>In vitro</i> study; basic research
Lymphomyosot® N	The immunopharmacological effects of homeopathic constituents of Lymphomyosot® N	Schmolz M., Metelmann H.	<i>BM</i> , 2001, 4; 177-183.	Effect of various potencies of constituents on IFNgamma, IL-6 and IL-10 levels	<i>In vitro</i> studies with blood cell cultures; basic research

KEY: BM = Biologische Medizin
 ARZN. FORSCH. = Arzneimittel Forschung
 II = Immunopharmacology and Immunotoxicology

HOMEOPATHY: OVERVIEW OF HUMAN CLINICAL TRIALS

Historical review of the main publications

A number of large-scale studies designed to evaluate the huge amount of homeopathic literature have been conducted, especially in the last 10 years. Organisations and institutes of great international prestige and importance have dealt with the issue of homeopathy.

All of them have concluded that homeopathy possesses therapeutic efficacy.

The characteristics of these studies are briefly summarised below.

- In 1991, **J. Kleijnen et al.** in the Netherlands evaluated 107 homeopathic clinical trials on the basis of a number of evaluation criteria also used in allopathic clinical trials (*Kleijnen J. et al. – Clinical trials in homeopathy. British Medical Journal, 1991; 302:316-323*). They selected 22 of these trials, which they judged to be of good quality (large number of patients recruited, type of randomisation, description of patients and methods, double blinding, and stated parameters for evaluation of results). 15 of these 22 trials, in which patients treated with the homeopathic drug were compared with patients who were untreated or treated with a placebo, demonstrated the therapeutic efficacy of the homeopathic drug. Kleijnen's meta-analysis was therefore mainly formulated on the basis of observational studies.

Globally, 81 of the 107 studies reviewed by Kleijnen et al. (76%) gave favourable results.

- In 1992, in view of the increasingly widespread use of non-conventional medicine (among which homeopathy stands out for the quantity and quality of the basic research and controlled clinical trials) and increased interest by the public and the media, the **US Congress** instituted the Office of Complementary Alternative Medicine, which later became NICAM (the National Institute of Complementary Alternative Medicine) within the National Institute of Health. NICAM has an annual budget of US\$ 100 million, and is responsible for laying down guidelines for

research into the validation of complementary medicines, formulating trial protocols and allocating funds for quality research.

- In May 1997, a report entitled “*Overview of data from homeopathic medicine trials*” was published by experts (clinical physicians, university pharmacologists and researchers in the homeopathic field) forming the **Homeopathic Medicine Research Group, Advisory Group 1**, set up by the **European Community**. These experts identified 377 clinical trials, short-listed 220, and reviewed 184. Detailed research lasting several months was conducted on the best trials, to evaluate their scientific value. The conclusions researched by the Advisory Group are unequivocal: **the number of significant results cannot be attributed to chance**. The analysis provided a random hypothesis value of $p < 0.001$. The Advisory Group remained very cautious, but expressly stated: “*The null hypothesis that homeopathy has no effect can be rejected with certainty; in other words, in at least one of the studies examined the patients treated with the homeopathic remedy received benefits compared with the control patients who received the placebo*”.
- In 1997, **K. Linde** et al. (Munich University) published the results of a meta-analysis of no less than 135 clinical trials which compared homeopathic drugs with a placebo in *Lancet* (Linde K. et Al. – *Are the clinical effects of homeopathy placebo effects? A meta-analysis of placebo-controlled trials. Lancet 1997; 350:834-843*). The authors concluded that “...*The results of this meta-analysis are not compatible with the hypothesis that the clinical effects of homeopathy are completely due to placebo*”. Linde had already published the favourable results of basic research studies conducted with homeopathic drugs in 1994 (Linde K. et al. – *Critical review and meta-analysis of serially agitated dilutions in experimental toxicology – Human Exp. Toxicol., 1994, 13:481-492*).
- In 1998, **E. Ernst** and **E.G. Hahn** described the state of the art in homeopathy, drawing conclusions similar to those reached by Linde in his 1997 meta-analysis (Ernst E., Hahn E.G. – *Homeopathy: a clinical appraisal. Oxford – Butterworth. Heinman, 1998*).
- In 1998, **P. Bellavite**, Associate Professor of General Pathology at Verona University, published a detailed review which collected, classified and analysed much of the available scientific literature that documents the effects of homeopathic remedies in clinical trials, together with studies conducted in the field of basic research. As regards clinical research, Bellavite reported on the most significant and methodologically reliable studies, drawing the conclusion that “*the common opin-*

ion that scientific proof of the clinical efficacy of homeopathy does not exist must therefore be refuted”.

Basic research is also actively developing, and some high-quality *in vitro* and *in vivo* studies that demonstrate the efficacy of homeopathy have been published in internationally recognised journals.

- Another meta-analysis conducted in **2000** on 24 studies relating to controlled, randomised clinical trials concluded that *“There is some evidence that homeopathic treatments are more effective than placebo”* (M. Cucherat et al. – *Evidence of clinical efficacy of homeopathy. A meta-analysis of clinical trials. Eur. J. Clin. Pharmacol.*, **2000**; 56:27-33).

Oddly enough, this body of trials and studies, some of which are of great institutional importance (such as the work of the Advisory Group set up by the European Community and the research conducted by NICAM in the US) has not been given sufficient prominence, either within the scientific community or by media.

This book is designed to fill the communication gap by systematically classifying the available studies, and in particular by reporting on the latest controlled clinical trials, which have become increasingly numerous in the past 2-3 years. The chapters which follow are devoted to classification and analysis of the best publications in the clinical field.

SCIENTIFIC STUDIES THAT PROVE THE EFFICACY OF HOMEOPATHY

Approximately **400** publications obtainable from international data bases (Medline, Embase, Biosis, the British Library, Stock Alert Service, SIGLE, Amed, etc.) which relate to **controlled clinical trials** of **nosographically defined disorders** (accounting for approx. 80% of the homeopathy studies conducted up to December 2001) demonstrate the **therapeutic efficacy** of the homeopathic drug tested.

No less than 98 studies (25%) were indexed in Medline between **1998** and **2001** alone, clearly indicating researchers' increasing interest in homeopathy.

We have excluded from our review studies which fail to comply with validated operational protocols; we relied in particular on the "Guidelines on planning, conduct and evaluation of multicentric studies" published in the German Official Federal Gazette No. 299, Vol. 4, 12, **1998**.

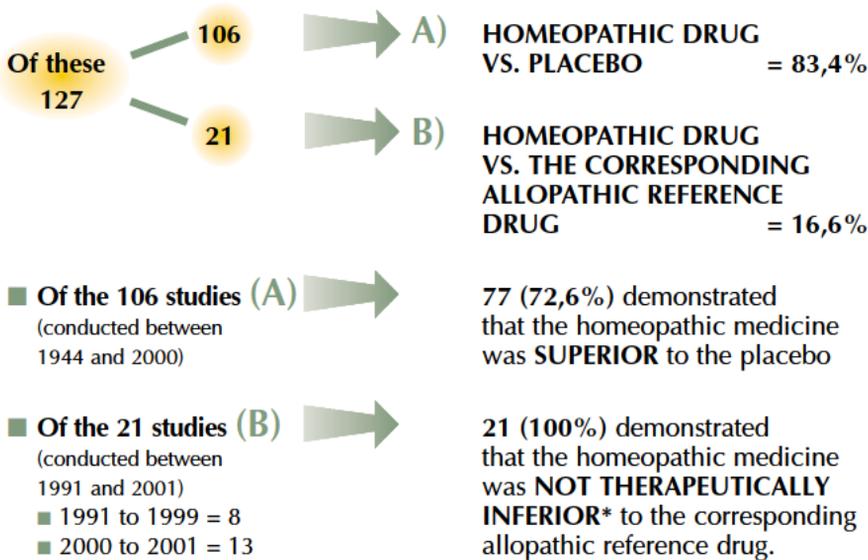
The exclusion criteria were consequently as follows:

- 1) open studies (only the global efficacy of homeopathy can be considered with this method, not the effect of each individual drug)
- 2) retrospective studies (which do not involve comparison with homogeneous groups)
- 3) studies in which a number of therapeutic techniques were associated
- 4) lack of homogeneity of the disorder among groups and within the same group
- 5) small number of patients recruited
- 6) defects in methodological procedure.

When these exclusion criteria were applied, the number of publications was reduced to approximately **200**.

We therefore examined **only** placebo-controlled trials and trials which compared a homeopathic medicine with the corresponding allopathic reference drug, some of which have been published in major international non-homeopathic journals such as the Lancet, Cancer, the British Medical Journal, the British Journal of Clinical Pharmacology, etc. (Table 2).

127 studies relating to controlled human clinical trials which provide valid, unequivocal information about the therapeutic effect of the drug in question have consequently been selected.



The tables below (Tables 1, 2 and 3) show the salient data and references of the 98 publications which demonstrated that a homeopathic medicine was superior to the placebo or not inferior to the corresponding allopathic reference drug.

* The term "NOT INFERIOR" means EQUAL or SUPERIOR TO

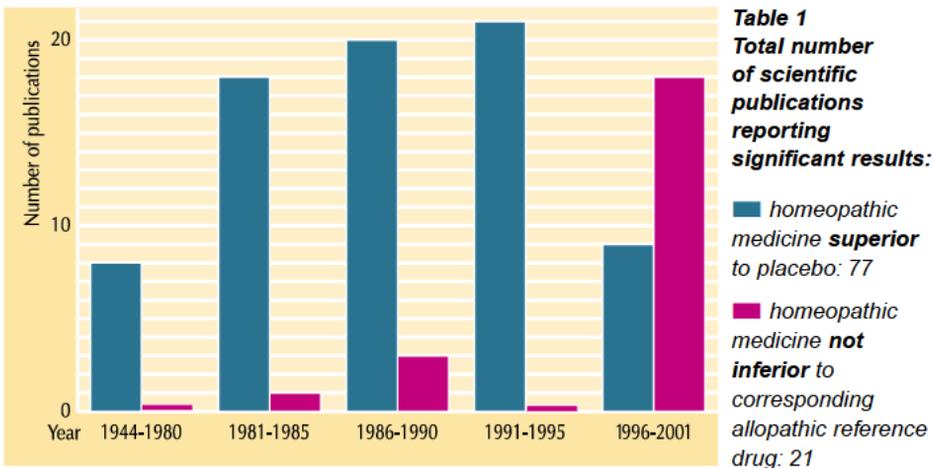


Table 2. LIST OF INTERNATIONAL AND NATIONAL NON-HOMEOPATHIC MEDICAL JOURNALS CITED IN THIS BOOK WHICH HAVE PUBLISHED THE RESULTS OF METHODOLOGICALLY RELIABLE CONTROLLED CLINICAL TRIALS THAT PROVE THE EFFICACY OF HOMEOPATHIC MEDICINES.

EXPERIMENTAL MODEL: HOMEOPATHIC MEDICINE VS PLACEBO	EXPERIMENTAL MODEL: HOMEOPATHIC MEDICINE VS CORRESPONDING ALLOPATHIC REFERENCE DRUG
<p>INTERNATIONAL SCIENTIFIC JOURNAL:</p> <ul style="list-style-type: none"> • LANCET • BRITISH MEDICAL JOURNAL • RHEUMATOLOGY • PHLEBOLOGY • PEDIATRICS • PÉDIATRIE • ALLERGOLOGIE • BRITISH JOURNAL OF CLINICAL PHARMACOLOGY • PEDIATRIC INFECTIVE DISEASES JOURNAL • AMERICAN REVUE OF RESPIRATORY DISEASES • ARCHIVES OF MEDICAL EMERGENCY • JOURNAL OF HEAD TRAUMA REHABILITATION • CANADIAN MEDICAL ASSOCIATION JOURNAL 	<p>INTERNATIONAL SCIENTIFIC JOURNAL:</p> <ul style="list-style-type: none"> • CANCER • THROMBOSIS RESEARCH • JOURNAL OF CLINICAL PHARMACOLOGY • ARCHIVES OF OTOLARYNGOLOGY/ HEAD AND NECK SURGERY • ARZNEIMITTEL FORSCHUNG/DRUG RESEARCH
<p>NATIONAL SCIENTIFIC JOURNAL</p> <ul style="list-style-type: none"> • ORTHOPÄDISCHE PRAXIS • THERAPIEWOCHE • KINDERARZT • FORSCHUNGSMEDIZIN • REVUE FRANÇAISE DE GYNÉCOLOGIE ET OBSTÉTRICIE 	

The subject of “publication bias” was tackled in the meta-analysis conducted by Kleijnen (1991). However, this problem obviously does not relate to medical/scientific publications only.

Many homeopathic studies with doubtful or negative results are rarely (if not exceptionally) published in homeopathy journals; they are more likely to be pu-

Table 3. LIST OF THE SELECTED CONTROLLED CLINICAL TRIALS GROUPED BY APPARATUS OR DISORDER

APPARATUS/DISORDER	TOTAL NUMBER	HOMEOPATHIC DRUG VERSUS PLACEBO	HOMEOPATHIC DRUG VERSUS ALLOPATHIC REFERENCE DRUG
ALLERGIES	11	9	2
ARTHROMYO-FASCIAL APPARATUS	12	8	4
GASTROINTESTINAL APPARATUS	9	8	1
RESPIRATORY APPARATUS, COMMON COLD/INFLUENZA SYNDROME AND ENT	20	15	5
SURGERY, PROPHYLAXIS, AND POST-OPERATIVE AND POST-RADIATION COMPLICATIONS	9	6	3
DERMATOLOGY	6	6	0
COAGULATION AND CIRCULATORY DISORDERS	6	5	1
GYNAECOLOGY AND OBSTETRICS	9	7	2
METABOLISM	5	5	0
NEUROLOGY	9	7	2
SUNDRY	2	1	1
TOTAL	98	77	21

blished and commented on with negative emphasis in official journals, even when certain subjects are not in line with their editorial strategy.

Conversely, many favourable results obtained with homeopathic medicines as a result of methodologically correct studies are published in homeopathic journals and merely ignored, censored, minimised or hyper-criticised by official allopathic journals, perhaps for fear of taking a favourable approach to a subject that is still controversial.

Despite the problem of publication bias, many prestigious national and international journals have published and given the right degree of emphasis to well-conducted homeopathic clinical trials (Table 2) simply because “the findings speak for themselves”, and science must take an impartial view.

SELECTED STUDIES GROUPED BY APPARATUS AND DISORDER

Allergies

9 placebo-controlled clinical trials of a homeopathic medicine

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Rhinitis and oculorhinitis	Wiesenauer M., Haussler S., Gaus W.	The treatment of pollinosis with Galphimia glauca.	<i>Fortsch. Med.</i> , 1983, 101: 811-814.	The homeopathic medicine proved therapeutically superior
Rhinitis and oculorhinitis	Wiesenauer M., Gaus W.	Double-blind trial comparing the effectiveness of the homeopathic preparation Galphimia potentisation D6, Galphimia dilution 10-6 and placebo on pollinosis.	<i>Arzneim. Forsch./Drug Res.</i> , 1985, 33: 1745-1747.	The homeopathic medicine proved therapeutically superior
Rhinitis and oculorhinitis	Reilly D.T., Taylor M.A.	Potent placebo or potency? A proposed study model with its initial findings using homeopathically prepared pollens in hayfever.	<i>Br. Hom. J.</i> , 1985, 74: 65-75.	The homeopathic medicine proved therapeutically superior
Rhinitis and oculorhinitis	Reilly D.T., Taylor M.A., McSharry C., Aitchinson T.	Is homeopathy a placebo response? Controlled trial of homeopathic potency, with pollen in hayfever as model.	<i>Lancet</i> , 1986, 2: 881-886.	The homeopathic medicine proved therapeutically superior
Rhinitis and oculorhinitis	Wiesenauer M., Gaus W., Haussler S.	The treatment of pollinosis with Galphimia glauca - double-blind clinical trial.	<i>Allergologie</i> , 1990, 13: 359-363.	The homeopathic medicine proved therapeutically superior
Rhinitis and oculorhinitis	Wiesenauer M., Ludtke R.	The treatment of pollinosis with Galphimia glauca D4 – a randomised placebo-controlled double-blind clinical trial.	<i>Phytomedicine</i> , 1995, 2: 3-6.	The homeopathic medicine proved therapeutically superior
Rhinitis and oculorhinitis	Taylor M.A., Reilly D., Llewellyn-Jones R.H., McSharry C., Aitchinson T.C.	Randomized controlled trial of homeopathy versus placebo in perennial allergic rhinitis with overview of four trial series.	<i>British Medical Journal</i> 2000 Aug, 19-26; 321 (7259): 471-6.	The homeopathic medicine proved therapeutically superior
Allergic bronchial asthma	Campbell J.H., Taylor M.A., Beattie N., McSharry C., Aitchinson T., Carter R., Stevenson R.D., Reilly D.T.	Is homeopathy a placebo response? A controlled trial of homeopathic immunotherapy in atopic asthma.	<i>Am. Rev. Resp. Dis.</i> , 1990, 141: A24.	The homeopathic medicine proved therapeutically superior

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Allergic bronchial asthma	Reilly D., Taylor M.A., Beattie N., Campbell J.H., McSharry C., Aitchinson T., Carter R., Stevenson R.D.	Is evidence for homeopathy reproducible?	<i>Lancet</i> , 1994 , 344: 1601-1606.	The homeopathic medicine proved therapeutically superior

2 clinical trials of a homeopathic medicine vs the corresponding allopathic reference drug

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Allergic rhinitis and oculorhinitis	Weiser M., Gegenheimer L.H., Klein P.	A randomized equivalence trial comparing the efficacy and safety of Luffa comp.-Heel nasal spray with cromolyn-sodium spray in the treatment of seasonal allergic rhinitis.	<i>Research in Complementary Medicine</i> , 1999/6 .	The homeopathic medicine was not therapeutically inferior* to the allopathic reference drug
Allergic rhinitis and oculorhinitis	Matusiewicz R.	The efficacy of Engystol in cases of bronchial asthma treated with corticosteroids.	<i>Biologische Medizin</i> , 1995 , 5; 242-246.	The homeopathic medicine was not therapeutically inferior* to the allopathic reference drug

The term "NOT INFERIOR" means EQUAL or SUPERIOR TO.

Arthromyofascial apparatus

8 placebo-controlled clinical trials of a homeopathic medicine

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Muscle cramps (2 drugs vs. placebo)	Mossinger P.	Demonstrations of efficacy.	<i>Allg. Hom. Zeitung</i> , 1976, 221: 26-31.	The homeopathic medicine proved therapeutically superior
Rheumatoid arthritis	Gibson R.G., Gibson S.L.M., Mc Neil A.D., Gray G.H., Carson W., Buchanan	Salicylates and homeopathy in rheumatoid arthritis: preliminary observations.	<i>Br. J. Clin. Pharmacol.</i> , 1978; 6: 391-395.	The homeopathic medicine proved therapeutically superior
Rheumatoid arthritis	Gibson R.G., Gibson S.L.M., Mc Neil A.D.	Homeopathic therapy in rheumatoid arthritis: evaluation by double-blind clinical therapeutic trial.	<i>Br. J. Clin. Pharmacol.</i> , 1980; 9: 453-459.	The homeopathic medicine proved therapeutically superior
Rheumatoid arthritis	Wiesnauer M., Gaus W.	Demonstration of efficacy of a homeopathic medicine in chronic polyarthritis. Randomised double-blind trial.	<i>Akt Rheumatol.</i> , 1991, 16: 1-9.	The homeopathic medicine proved therapeutically superior
Tibiotarsal sprain (astragalus)	Zell J., Connert W.D., Mau J.	Treatment of acute sprains of the ankle: A controlled double-blind trial to test the effectiveness of a homeopathic ointment.	<i>Forts. der Med.</i> , 1988 96/62-100/70.	The homeopathic medicine proved therapeutically superior
Fibromyositis	Fisher P., Greenwood A., Huskisson E.C.	Effect of homeopathic treatment on fibrositis (primary fibromyalgia).	<i>Brit. Med. J.</i> , 1989, 299: 365-366.	The homeopathic medicine proved therapeutically superior
Trauma	Gibson J., Haslam Y., Laurenson L., Newman P.	Double blind trial of Arnica in acute trauma patients.	<i>Homoeopathy</i> , 1991, 41: 54-55.	The homeopathic medicine proved therapeutically superior
Haemarthrosis	Thiel W., Borho B.	The treatment of recent traumatic blood effusions of the knee joint.	<i>Biol. Medizin</i> , 1991, 20: 506-515.	The homeopathic medicine proved therapeutically superior

4 clinical trials of a homeopathic medicine vs the corresponding allopathic reference drug

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Osteoarthritis of the knee	Nahler G., Metelmann H., Sperber H.	Treating osteoarthritis of the knee with a homeopathic preparation – Results of a randomized, controlled, clinical trial in comparison to hyaluronic acid.	<i>Orthopädische Praxis</i> , 1996, 5.	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug
Osteoarthritis of the knee	Maronna U., Weiser M., Klein P.	Oral treatment of osteoarthritis of the knee with Zeel S tablets.	<i>Orthopädische Praxis</i> , 2000, 5.	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug
Osteoarthritis of the knee	Van Haselen R.A.	A randomized controlled trial comparing topical piroxican gel with a homeopathic gel in osteoarthritis of the knee.	<i>Rheumatology (Oxford)</i> , 2000 Jul.; 39 (7): 714-9.	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug
Backache	Stam C., Bonnet M.S., Van Haselen R.A.	The efficacy and safety of a homeopathic gel in the treatment of acute low back pain: a multi-centre, randomised, double-blind comparative clinical trial.	Br. Homeopath. J., 2001 Jan; 90(1): 21-8.	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug

The term "NOT INFERIOR" means EQUAL or SUPERIOR TO.

Coagulation and circulatory disorders

5 placebo-controlled clinical trials of a homeopathic medicine

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Haematoma	Bourgois J.C.	Protection of the venous system in patients with perfused breast cancer. Double-blind clinical trial.	<i>Université Paris Nord (Thesis)</i> , 1983.	The homeopathic medicine proved therapeutically superior
Haematoma	Amodeo C., Dorfman P., Ricciotti F., Tetau M., Veroux P.F.	Evaluation of the action of Arnica 5CH on vein disorders after lengthy perfusion.	<i>Cahiers Biother.</i> , 1988, 98: 77-82.	The homeopathic medicine proved therapeutically superior
Varicose veins	Ernst E., Saradeth T., Resch K.L.	Complementary treatment of varicose veins. A randomised, placebo-controlled, double-blind trial.	<i>Phlebology</i> , 1990, 5: 157-163.	The homeopathic medicine proved therapeutically superior
Filariasis	Subramanyam V.R., Mishra N., Ray Y., Rakshit G., Pattnaik N.M.	Homeopathic treatment of filariasis. Experience in an Indian rural setting.	<i>Br. Hom. J.</i> , 1990, 79: 157-160.	The homeopathic medicine proved therapeutically superior
Asymptomatic filariasis	Kumar A., Mishra N.	Effect of homeopathic treatment of filariasis. A single-blind 69-months follow-up study in an endemic village in Orissa.	<i>Br. Hom. J.</i> , 1994, 83: 216-219.	The homeopathic medicine proved therapeutically superior

1 clinical trial of a homeopathic medicine vs the corresponding allopathic reference drug

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Haemostasis	Doutremepuich C., Pailley D., Anne M.C., De Seze O., Paccalin J., Quilichini R.	Template bleeding time after ingestion of ultra low dosages of acetylsalicylic acid in healthy subjects. Preliminary study.	<i>Thrombosis Res.</i> , 1987, 48: 501-504.	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug

The term "NOT INFERIOR" means EQUAL or SUPERIOR TO.

Dermatology

6 placebo-controlled clinical trials of a homeopathic medicine

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Skin lesions	Paterson J.	Report on Mustard Gas Experiment.	<i>J. Am. Inst. Homeopathy</i> , 1944 , 37: 47-50, 88-92.	The homeopathic medicine proved therapeutically superior
Skin lesions	Balzarini A., Felisi E., Martini A., De Donno F.	Efficacy of homeopathic treatment of skin reaction during radiotherapy for breast cancer: a randomised, double-blind clinical trial.	<i>Br. Homeopath. J.</i> , 2000 Jan; 89 (1): 8-12.	The homeopathic medicine proved therapeutically superior
Pyodermitis	Mossinger P.	The therapeutic efficacy of Hepar sulfuris calcareum D4 in pyodermitis and boils.	<i>Allg. Hom. Zeitung</i> , 1980 , 225: 22-28.	The homeopathic medicine proved therapeutically superior
Burns	Leaman A.M., Gorman D.	Cantharis in the early treatment of minor burns.	<i>Arch. Emerg. Med.</i> , 1989 , 6: 259-261.	The homeopathic medicine proved therapeutically superior
Dermatosis	Schwab G.	Can the effect of homeopathic substances in high potencies be demonstrated experimentally? A controlled, cross-over double blind study in patients with skin conditions.	<i>Proc. 45th LMHI Congr., Barcelona, Spain</i> , 1990 , 166-169.	The homeopathic medicine proved therapeutically superior
Plantar warts	Labrecque M., Audet D., Latulippe L.G., Drouin J.	Homeopathic treatment of plantar warts.	<i>Ca. Med. Assoc. J.</i> , 1992 , 146: 1749-1753.	The homeopathic medicine proved therapeutically superior

Gastrointestinal apparatus

8 placebo-controlled clinical trials of a homeopathic medicine

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Pharyngitis	Mossinger P.	The treatment of pharyngitis with Phytolacca.	<i>Allg. Hom. Zeitung</i> , 1973; 218: 111-121.	The homeopathic medicine proved therapeutically superior
Gastritis	Ritter H.	Double-blind homeotherapeutic study and the issues involved.	<i>Hippokrates</i> , 1966, 12: 472-476.	The homeopathic medicine proved therapeutically superior
Irritable colon	Rahlfis V.W., Mossinger P.	Asa foetida in the treatment of irritable colon: double-blind clinical trial.	<i>Dtsch. Med. Wschr.</i> , 1979, 104: 140-143.	The homeopathic medicine proved therapeutically superior
Cholecystitis	Mossinger P.	Homeopathy and naturopathy. How to overcome conflicts.	<i>Hippokrates (Stuttgart)</i> , 1984, 165-169.	The homeopathic medicine proved therapeutically superior
Anal fissures	Bignamini M., Saruggia M., Sansonetti G.	Homeopathic treatment of anal fissures using nitricum acidum.	<i>Berl. J. Res. Hom.</i> , 1991, 1 (4/5): 286-287.	The homeopathic medicine proved therapeutically superior
Diarrhoea (paediatric cases)	Jacobs J., Jimenez L.M., Gloyd S.S., Carares F.E., Gaitan M.P., Crothers D.	Homeopathic treatment of acute childhood diarrhoea. A randomised clinical trial in Nicaragua.	<i>Br. Hom. J.</i> , 1993, 82: 83-86.	The homeopathic medicine proved therapeutically superior
Diarrhoea (paediatric cases)	Jacobs J., Jimenez L.M., Gloyd S.S., Gale J.L., Crothers D.	Treatment of acute childhood diarrhoea. A randomised clinical trial in Nicaragua.	<i>Pediatrics</i> , 1994, 93: 719-725.	The homeopathic medicine proved therapeutically superior
Diarrhoea (paediatric cases)	Jacobs J., Jimenez L.M., Malthouse S., Chapman E., Crothers D., Masuk M., Jonas W.B.	Homeopathic treatment of acute childhood diarrhoea: results from a clinical trial in Nepal.	<i>J. Altern. Complement. Med.</i> , 2000 Apr; 6 (2): 131-9.	The homeopathic medicine proved therapeutically superior

1 clinical trial of a homeopathic medicine vs the corresponding allopathic reference drug

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Vomiting	Stukalova E.N.	Efficacy of homotoxicological treatment in early toxemia of pregnancy.	<i>B.T.</i> , 2000, 4 (Ukrainian edition)	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug

The term "NOT INFERIOR" means EQUAL or SUPERIOR TO.

Gynaecology and obstetrics

7 placebo-controlled clinical trials of a homeopathic medicine

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Menopause	Gauthier J.E.	Comparative therapeutic study of the action of clonidine and Lachesis muta in the treatment of hot flushes in the menopause.	<i>Université de Bordeaux (Thesis), 1983.</i>	The homeopathic medicine proved therapeutically superior
Leucorrhoea	Carey H.	Double blind clinical trial of Borax and Candida in the treatment of vaginal discharge.	<i>Comm. Br. Hom. Res. Grp., 1986</i> March:12-14.	The homeopathic medicine proved therapeutically superior
Premenstrual syndrome	Lepaisant C.	Therapeutic demonstrations in homeopathy: treatment of breast tension and mastodynia in premenstrual syndrome.	<i>Rev. Fr. Gynecol. Obstét., 1995,</i> 90: 94-95.	The homeopathic medicine proved therapeutically superior
Childbirth (pain)	Coudert M.	Experimental study of the action of Caulophyllum in false labour.	<i>Université de Limoges (Thesis), 1981.</i>	The homeopathic medicine proved therapeutically superior
Childbirth (pain)	Dorfman P., Lasserre M.N., Tetau M.	Preparation for childbirth with homeopathy: a double-blind placebo-controlled trial.	<i>Cahiers de Biothérapie, 1987,</i> 94: 77- 81.	The homeopathic medicine proved therapeutically superior
Childbirth (labour)	Eid P., Felisi E., Sideri M.	Super placebo or pharmacological action? A double-blind randomised trial with a homeopathic drug (Caulophyllum thalictroides) during labour.	<i>Proc. V Congr. O.M.H.I., Paris, 1994.</i>	The homeopathic medicine proved therapeutically superior
Florid condylomatosis	Destro Castaniti M.	The use of Transfactor 11 in HPV infections (160 cases).	<i>La Medicina Biologica, 2000,</i> 4; 95: 100.	The homeopathic medicine proved therapeutically superior

2 clinical trials of a homeopathic medicine vs the corresponding allopathic reference drug

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Functional infertility	Lai G.	Homotoxicological treatment of female functional infertility: clinical trial.	<i>La Medicina Biologica</i> , 2000, 4:81-86.	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug
Toxaemia in pregnancy	Stukalova E.N.	Efficacy of homotoxicological treatment in early toxaemia of pregnancy.	<i>BT</i> , 2000, 4 (Ukrainian edition)	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug

The term "NOT INFERIOR" means EQUAL or SUPERIOR TO.

KEY: BT = Biomedical Therapy

Metabolism

5 clinical trials of a homeopathic medicine vs placebo

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Diabetes mellitus	Fabbro V., Gargiulo P., Minelli E.	Multicentric study of the action of the homeopathic complex R40 in the treatment of hyperglycaemia.	<i>Omeopatia Oggi</i> , 1994, 5 (10): 1-16.	The homeopathic medicine proved therapeutically superior
Diabetic retinopathy	Zicari D., Ricciotti F., Vingolo E.M., Zicari N.	Evaluation of the angioprotective action of arnica preparations in the treatment of diabetic	<i>Boll. Oculist.</i> , 1992, 71: 841-848.	The homeopathic medicine proved therapeutically superior
Obesity	Werke W., Lehmann M., Galland F.	Comparative controlled trial of the efficacy of the plant-based homeopathic medicine <i>Heliantus tuberosus</i> D1 in the complementary treatment of	<i>Therapiewoche</i> , 1994, 44: 34-39.	The homeopathic medicine proved therapeutically superior
Complications of haemodialysis	Hariveau E.	overweight patients. Clinical research at the Boiron Institute.	<i>Homéopathie</i> , 1987/5; 55-8.	The homeopathic medicine proved therapeutically superior
Complications of haemodialysis	Saruggia M., Corghi E.	Effects of homeopathic dilutions of <i>China rubra</i> on intradialytic symptomatology in patients treated with	<i>Br. Hom. J.</i> , 1992, 81: 86-88.	The homeopathic medicine proved therapeutically superior

Neurology

7 clinical trials of a homeopathic medicine vs placebo

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Dental neuralgia	Albertini H., Godberg W.	Homeopathic treatment of dental neuralgia using Arnica and hypericum: a summary of 60 observations.	<i>Homéopathie Française</i> , 1984, 71: 47-49.	The homeopathic medicine proved therapeutically superior
Kinetosis (motion sickness)	Ponti M.	Evaluation of homeopathic treatment of motion sickness; results of 93 observations.	<i>In: Recherches Homéopathiques (Boiron J., Belon P., Hariveau E., eds.). Fondation Française pour la Recherche en Homéopathie</i> , 1986. Lyon: 71-74.	The homeopathic medicine proved therapeutically superior
Kinetosis (motion sickness)	Dexpert M.	Prevention of motion sickness with Cocculine.	<i>Homéopathie Franc.</i> , 1987, 75: 353-355.	The homeopathic medicine proved therapeutically superior
Aphasia	Master F.J.	Scope of homeopathic drugs in the treatment of Broca's aphasia.	<i>Proc. 42nd Congr. LMHI</i> , 1987, Arlington, USA: 330-334.	The homeopathic medicine proved therapeutically superior
Migraine	Brigo B., Serpelloni G.	Homeopathic treatment of migraines: a randomized double-blind controlled study of sixty cases.	<i>Berl. J. Res. Hom.</i> , 1991, 1 (2): 98-106.	The homeopathic medicine proved therapeutically superior
Head injury	Chapman E.H., Weintraub R.J., Milburn H.A., Pirozzi T.O., Woo E.	Homeopathic treatment of mild traumatic brain injury: a randomized, double blind placebo-controlled clinical trial.	<i>J. Head Trauma Rehabil.</i> , 1999 Dec; 14 (6): 521-42.	The homeopathic medicine proved therapeutically superior
Migraine	Straumsheim P., Borchgrevink C., Mowinckel P., Kierulf H., Hafslund D.	Homeopathic treatment of migraine: a double blind, placebo controlled trial of 68 patients.	<i>Br. Homeopath. J.</i> , 2000 Jan; 89 (1) 4-7.	The homeopathic medicine proved therapeutically superior

2 clinical trials of a homeopathic medicine vs the corresponding allopathic reference drug

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Vertigo	Weiser M.	Homeopathic vs conventional treatment of vertigo.	Arch. Of Otolaryngology. Head and Neck Surgery, 1998, August.	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug
Vertigo	Wolschner U., Strösser W., Weiser M., Klein P.	Vertigo therapy: Cocculus -heel® versus Dimenhydrinate.	<i>BM</i> , 2001, 4. Publicato in italiano (2)	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug

The term "NOT INFERIOR" means EQUAL or SUPERIOR TO.

KEY: BM = Biologische Medizin

Respiratory apparatus, common cold/influenza syndrome and ENT

15 placebo-controlled clinical trials of a homeopathic medicine

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Infections of the upper airways	Hourest P.	Acknowledgement of the efficacy of homeopathy.	<i>Université P. et M. Curie (Thesis)</i> . Paris, France, 1981.	The homeopathic medicine proved therapeutically superior
Infections of the upper airways	Lecoq P.L.	Therapeutic possibilities in the treatment of influenza syndromes.	<i>Cah. Biothér.</i> , 1985, 87: 65-73.	The homeopathic medicine proved therapeutically superior
Infections of the upper airways	Bordes L.R., Dorfman P.	Evaluation of the antitussive action of Drosetux syrup; double-blind placebo-controlled clinical trial.	<i>Cahiers d'Otorhinolaryngologie</i> , 1986, 21: 731-734.	The homeopathic medicine proved therapeutically superior
Infections of the upper airways	Casanova P., Gerard R.	Results of three years of randomised multicentric studies with Oscillocoquinum/ placebo.	<i>Proposta Omeopatica</i> 3, Anno IV, ottobre 1988.	The homeopathic medicine proved therapeutically superior
Coryza	Mossinger P.	Study of treatment of rhinorrhoea with Euphorbium D3.	<i>Allg. Hom. Zeitung</i> , 1982, 227: 89-95.	The homeopathic medicine proved therapeutically superior
Otitis media	Mossinger P.	The treatment of otitis media with Pulsatilla.	<i>Kinderarzt</i> , 1985, 16: 581-582.	The homeopathic medicine proved therapeutically superior
Otitis media	Jacobs J., Springer D.A., Crothers D.	Homeopathic treatment of acute otitis media in children: a preliminary randomised placebo-controlled trial.	<i>Pediatr. Infect. Dis. J.</i> , 2001 Feb; 20 (2): 177-83.	The homeopathic medicine proved therapeutically superior
Glue ear	Harrison H., Fixsen A., Vickers A.	A randomised comparison of homeopathic and standard care for the treatment of glue ear in children.	<i>Complemen. Ther. Med.</i> , 1999, Sept; 7 (3): 132-5.	The homeopathic medicine proved therapeutically superior
Sinusitis	Wiesenauer M., Gaus W., Bohnacker U., Haussler S.	Study of the efficacy of homeopathic compound preparations in sinusitis. Results of a double-blind randomised out-patient study.	<i>Arzneim. Forsch./Drug Res.</i> , 1989, 39: 620-625.	The homeopathic medicine proved therapeutically superior
Sinusitis	Weiser M., Clasen B.P.	Controlled double-blind study of a homeopathic sinusitis medication.	<i>Biol. Ther.</i> , 1994, 13: 4-11.	The homeopathic medicine proved therapeutically superior
Influenza syndrome	Ferley J.P., Zmirou D., D'Adhemar D., Balducci F.	A controlled evaluation of a homeopathic preparation in influenza-like syndromes.	<i>Br. J. Clin. Pharmac.</i> , 1989, 27: 329-335.	The homeopathic medicine proved therapeutically superior

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Influenza syndrome	Saruggia M.	Influenza and viral respiratory infections.	<i>Medicina Naturale</i> , 1994/6.	The homeopathic medicine proved therapeutically superior
Influenza syndrome	Heilmann A.	A combination injection preparation as a prophylactic for flu and common colds.	<i>Biol. Ther.</i> , 1994, 7: 249-253.	The homeopathic medicine proved therapeutically superior
Influenza syndrome	Saruggia M.	The preventive effect of Oscillococcinum in influenza-like syndromes. Results of a multicentric study.	<i>Medicina Naturale</i> , 1995/6.	The homeopathic medicine proved therapeutically superior
Bronchial asthma	Matusiewicz R.	The efficacy of Engystol in cases of bronchial asthma treated with corticosteroids.	<i>La Medicina Biologica</i> , 1996, 1; 3-8.	The homeopathic medicine proved therapeutically superior

5 clinical trials of a homeopathic medicine vs the corresponding allopathic reference drug

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Infections of the upper airways	Arrighi A.	Evaluation of clinical efficacy in a homotoxicologic protocol for prevention of recurrent respiratory infections in pediatrics.	<i>La Medicina Biologica</i> , 2000, 3: 13-21.	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug
Infections of the upper airways	Riley D., Fisher M., Singh B., Haidvogel M., Heger M.	Homeopathy and Conventional Medicine: an outcome study comparing effectiveness in a primary care setting.	<i>The Journal of Alternative and Complementary Medicine</i> , 2001, Vol 7, N° 2; 149-	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug
Common cold	Gassinger C.A., Wunstel G.	A controlled clinical trial for testing the efficacy of the homeopathic drug Eupatorium perfoliatum D2 in the treatment of common cold.	<i>Arzheim Forsch./Drug Res.</i> , 1981, 31: 732-736.	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug
Common cold	Maiwald L., Weinfurter T., Mau J., Connert W.D.	The therapy of the common cold with a combination homeopathic preparation, compared with treatment with acetylsalicylic acid: a controlled randomized, single-blind study.	<i>Arzheim Forsch./Drug Res.</i> , 1988/4.	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug
Otitis media	Kruse K.	Subject reported in the volume.	<i>Edition Forsch. Hippokrates Verlag, Stuttgart</i> ,	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug

The term "NOT INFERIOR" means EQUAL or SUPERIOR TO.

Sundry

1 placebo-controlled clinical trial of a homeopathic medicine

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
HIV infection	Rastogi D.P., Singh V.P., Singh V., Dey S.K., Rao K.	Homeopathy in HIV infection: a trial report of double-blind placebo-controlled study.	<i>Br. Homeopath. J.</i> , 1999 Apr; 88 (2): 49-57.	The homeopathic medicine proved therapeutically superior

1 clinical trial of a homeopathic medicine vs the corresponding allopathic reference drug

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Conjunctivitis	Küstermann R.W., Weiser M., Klein P.	Antihomotoxic treatment of conjunctivitis. Results of a prospective, controlled, cohort study.	<i>BM</i> , 2001, 3.	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug

The term "NOT INFERIOR" means EQUAL or SUPERIOR TO.

KEY: BM = Biologische Medizin

Surgery, prophylaxis, postoperative and post-radiation complications

6 placebo-controlled clinical trials of a homeopathic medicine

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Dynamic ileus	Valero E.	Study of the preventive action of Raphanus sativus 7CH on the post-operative recovery time of intestinal transit (80 cases); and of Pyrogenium 7CH on post-operative infections (128 cases).	<i>Université de Grenoble (Thesis), 1981.</i>	The homeopathic medicine proved therapeutically superior
Dynamic ileus	Chevrel J.P., Saglier J., Destable M.D.	Recovery of intestinal transit in digestive surgery. Homeopathic action of opium.	<i>Press Med., 1984, 13: 833.</i>	The homeopathic medicine proved therapeutically superior
Dynamic ileus	Aulagnier G.	The action of post-operative homeopathic treatment.	<i>Homéopathie, 1985, 6: 42-45.</i>	The homeopathic medicine proved therapeutically superior
Post-operative infections	Valero E.	Study of the preventive action of Raphanus sativus 7CH on the post-operative recovery time of intestinal transit (80 cases); and of Pyrogenium 7CH on post-operative infections (128 cases).	<i>Université de Grenoble (Thesis), 1981.</i>	The homeopathic medicine proved therapeutically superior
Post-operative psychomotor agitation	Alibeu J.P., Jobert J.	Aconite in homeopathic relief of post-operative pain and agitation in children.	<i>Pédiatrie, 1990, 45: 465-466.</i>	The homeopathic medicine proved therapeutically superior
Post-extraction complications (dental cases)	Michaud J.	The action of Apis mellifica and Arnica montana in preventing post-operative oedema in maxillofacial surgery in a clinical trial involving 60 cases.	<i>Université de Nantes (Thesis), 1981.</i>	The homeopathic medicine proved therapeutically superior

3 clinical trials of a homeopathic medicine vs the corresponding allopathic reference drug

DISORDER	AUTHORS	ORIGINAL/TRANSLATED	PUBLICATION	EFFECT
Post-extraction complications (dental cases)	Ribot Florit J.	Effects of Arnica comp.-Heel® on post-extraction pain, inflammation and bleeding.	<i>Medicina Biologica (in Spanish)</i> 2001/1.	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug
Prevention of post-operative sepsis complications	Bononi M.	Echinacea comp. Forte S in the prophylaxis of post-operative infections. A comparative study versus ceftazidime and ceftriaxone.	<i>La Medicina Biologica</i> , 2001, 1: 17-22.	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug
Prevention of complications of chemotherapy	Oberbaum M., Yaniv Y., Ben-Gal J., Ben-Zvi N., Freedmann L.S., Branski D.	A randomised, controlled clinical trial of the homeopathic medication Traumeel S in the treatment of chemotherapy-induced stomatitis in children undergoing stem cell transplantation.	<i>Cancer</i> – August 1, 2001/Vol 92/ Number 3.	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug

The term "NOT INFERIOR" means EQUAL or SUPERIOR TO.

SYNOPTIC ANALYSIS OF 10 CLINICAL TRIALS

In order to illustrate the basic findings of some clinical publications selected from the extensive literature available, this chapter describes **10 studies** published between 1988 and 2001 which conform to the “Guidelines on planning, conduct and evaluation of multicentric studies” published in the German Official Federal Gazette No. 299, Vol. 4, 12, 1998.

We have chosen **only** studies which compare a homeopathic drug (or homeopathic protocol) with the corresponding allopathic reference drug, in accordance with the latest version of the Helsinki Declaration (September 2001): *“The benefits, risks, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic, and therapeutic methods.”*

The quality of clinical studies in homeopathy has considerably improved since the 1980s, and especially in the past 2-3 years, has reached the international standards of the best studies conducted in the allopathic field.

Of the 21 controlled clinical trials vs allopathic reference drug selected by us:

- 8 were published in **non-homeopathic** scientific journals, and
- 13 were published in prestigious homeopathic scientific journals.

No less than 13 of the 21 controlled clinical homeopathic trials vs the corresponding allopathic reference drug referred to in the previous chapter were published between 2000 and 2001. This clearly indicates the growing interest of researchers in this field and the real possibilities of validating homeopathic treatment in accordance with internationally accredited procedures.

In addition to the experimental data, we have added a comparative evaluation of the costs of homeopathic treatment and the corresponding allopathic treatment. In most cases the homeopathic treatment is cheaper, and in some cases the difference is considerable.

Note: The tables set out below are the original tables that appeared in the various publications.



10 SELECTED CLINICAL TRIALS

SYNOPTIC ANALYSIS

AUTHORS: MAIWALD L., WEINFURTNER T., MAU J.,
CONNERT W.D.

TITLE: **The therapy of the common cold with a
complex homeopathic medicine,
compared with treatment with acetylsalicylic
acid: a controlled randomized, single-blind study.**

PUBLISHED IN: Azneimittel Forschung/Drug Research, 1988/4.

**PUBLISHED
IN ENGLISH:** Biological Therapy Journal of Natural Medicine
Vol. XI No. 1 - pp. 2-8

**PUBLISHED
IN ITALIAN:** Riv. Ital. di Omotossicologia, 1988/4, 25:30.

- **TRIAL
METHODOLOGY:** Controlled, randomised, single-blind clinical
trial.
The clinical trial meets the criteria of
homogeneity, identifies a primary objective, and
dimensions the sample in accordance with
statistical criteria of reliability.

- **COUNTRY:** Germany, Military Hospital, Internal Medicine
Department

- **NUMBER OF
PATIENTS RECRUITED:** 170 conscripts and regular soldiers

- **DISEASE:** common cold syndrome

- **TREATMENT:**  **homeopathic group = Aconitum-Heel® = 88 patients**
allopathic group = Acetylsalicylic acid = 87 patients

- **DURATION OF THE TRIAL:** 10 days

- **DOSE:**

 - Aconitum-Heel® 3 tablets t.i.d for 10 days
 - ASA from 1st to 4th day: 500 mg t.i.d.
 - from 5th to 10th day: 500 mg once a day

- **INCLUSION CRITERIA:**

<ul style="list-style-type: none"> at least 3 of the following: - abnormal fatigue - loss of appetite - excessive thirst - insomnia - chills - excessive perspiration - runny nose - cough 	<ul style="list-style-type: none"> at least 2 of the following: - sore throat - earache - aches in limbs - headache 	<ul style="list-style-type: none"> at least 1 of the following: - nasal secretion - swelling of lymph glands - eardrum retraction - sounds indicating bronchitis.
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- **EVALUATION CRITERIA:**

 - therapeutic success within 4 days
 - therapeutic success within 10 days

- **THERAPEUTIC EFFICACY:**

 - A)** 115 cases were analysed within the 4th day of treatment
 - treatment effective:30% of patients in the Aconitum-Heel® group
 - 20% of patients in the ASA group
 - B)** after the 4th day [excluding cases (A)]
 - treatment effective:70% of patients in the Aconitum-Heel® group
 - 20% of patients in the ASA group

- **AUTHORS' CONCLUSIONS:**

"The success rate for patients cured by the 4th (or 5th) and by the 10th (or 11th) day was higher in the group treated with Aconitum-Heel® than in the group treated with ASA (difference not statistically significant)".

- **FINAL RESULT:**

Aconitum-Heel® is not inferior to acetylsalicylic acid in the treatment of the common cold syndrome.

TOTAL COST:	homeopathic treatment € 12.40	
	allopathic treatment € 2.45	

	Test group treated with <i>Aconitum Heel</i> ®	Control group treated with ASA	Total
Total	30% (17-42%)	20% (12-36%)	26% (18-35%)
January - March 1984	40% (20-56%)	20% (5-42%)	30% (18-44%)
January - March 1985	40% (5-85%)	30% (4-71%)	30% (10-65%)
July 1985 - March 1986	20% (6-38%)	25% (9-45%)	20% (11-35%)

A “therapeutic success within 4 days”, expressed as a %, with the corresponding 95% confidence interval.

	Test group treated with <i>Aconitum Heel</i> ®	Control group treated with ASA	Total
Total	70% (55-84%)	20% (46-77%)	26% (56-77%)
January - March 1984	75% (55-89%)	20% (46-88%)	30% (58-85%)
January - March 1985	25% (0-81%)	30% (22-96%)	30% (19-81%)
July 1985 - March 1986	80% (44-97%)	25% (23-77%)	20% (41-81%)

A “therapeutic success within 10 days”, expressed as a %, with the corresponding 95% confidence interval.

2

AUTHORS: NAHLER G., METELMANN H., SPERBER H.

TITLE: **Treatment of osteoarthritis of the knee with a homeopathic medicine – Results of a randomized, controlled, clinical trial in comparison to hyaluronic acid.**

PUBLISHED IN: Orthopädische Praxis, 1996, 5.

PUBLISHED IN ENGLISH: Biomedical Therapy 1998;16(2):186-191

PUBLISHED IN ITALIAN: La Medicina Biologica, 1997/2; 11:16.

- **TRIAL METHODOLOGY:** Controlled, multicentric, randomised, single-blind trial.
The clinical trial meets the criteria of homogeneity, identifies a primary objective, and dimensions the sample in accordance with statistical criteria of reliability.
- **COUNTRY:** Germany and Austria – 12 orthopaedic clinics
- **NUMBER OF PATIENTS RECRUITED:** 121 patients (aged 35 to 85 years old) for whom surgical treatment was not likely in the immediate future.
103 patients completed the protocol.
- **DISEASE:** primary osteoarthritis of the knee.
- F) ■ **TREATMENT:**
 - homeopathic group = Zeel® T = 57 patients (12 M, 45 F)
 - allopathic group = Hyalart® = 57 patients (11 M, 46 F)
- **DURATION OF THE TRIAL:** 5 weeks
- **PROCEDURE AND DOSE:**
 - homeopathic group:** 10 intra-articular infiltrations of Zeel® T (2 ml = 1 ampoule) twice a week
 - allopathic group:** 5 intra-articular infiltrations of Hyalart® (2 ml = 1 ampoule)

- INCLUSION CRITERIA:
 - 1) primary osteoarthritis of the knee clinically diagnosed on the basis of statement of pain symptoms in the knee
 - 2) radiological finding of osteoarthritis of the knee
 - 3) constant pain for at least 3 months, with no signs of acute active inflammation
 - 4) written informed consent.

- EXCLUSION CRITERIA:
 - 1) secondary osteoarthritis of the knee
 - 2) acute active osteoarthritis
 - 3) bedridden patients
 - 4) patients who had received intra-articular corticosteroid treatment in the 2 months prior to recruitment
 - 5) mild pain.

- EVALUATION CRITERIA:
 - subjective sensitivity to pain
 - subjective sensitivity to joint pain at night
 - duration of stiffness in the morning
 - maximum walking ability
 - tolerability of drug (after 5 weeks' treatment)
 - time taken to walk up and down a standard staircase
 - final evaluation by doctor and patient
 - modification of pain on the VAS (visual analog scale)

- THERAPEUTIC EFFICACY:

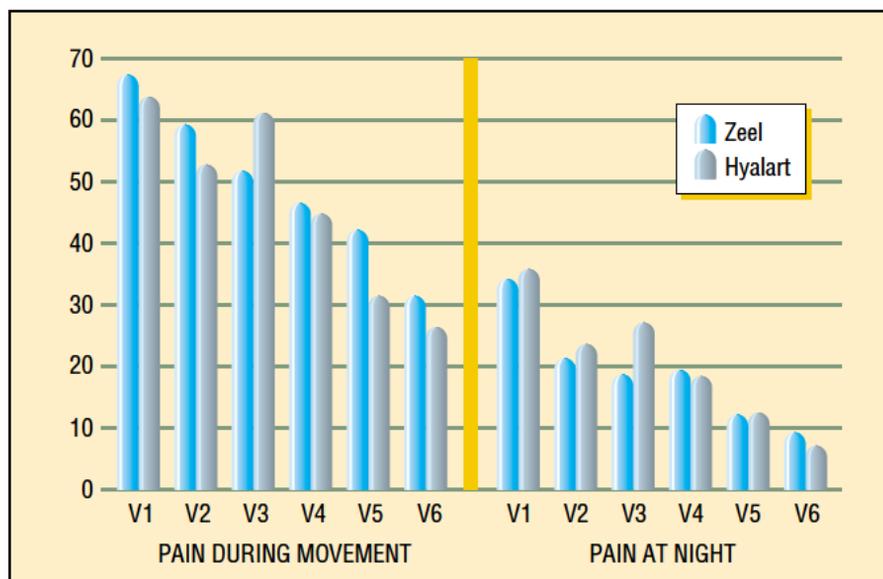
when the difference in efficacy between Zeel® T and Hyalart® was observed with the Wilcoxon test, the two treatments proved equivalent (pain on movement: $p = 0.42$; pain at night: $p = 0.3$; duration of stiffness in the morning: $p = 0.92$): 87.3% of the patients treated with Zeel® T and 93.0% of those treated with Hyalart® presented a considerable improvement in the global symptoms. The subjective evaluation by the patients in both groups was more favourable than the evaluation by the doctors.

- SIDE EFFECTS:

6 Zeel® T patients and 13 Hyalart® patients: intra-articular effusion evacuated by arthrocentesis.

- TOLERABILITY: excellent for both drugs
- AUTHORS' CONCLUSIONS: *"The therapeutic efficacy of the two drugs (pain relief, increased functional capacity and quality of life) is equivalent".*
- FINAL RESULT: Intra-articular injections of Zeel® are not inferior to intra-articular injections of hyaluronic acid in the treatment of primary osteoarthritis of the knee.

TOTAL COST: homeopathic treatment € 20.70
~~allopathic treatment € 173.55~~



Average pain following the treatment with Zeel® and Hyalart® (pain on the VAS scale: 0 mm = no pain; 100 mm = maximum pain level. V1 = Baseline; V2 – V6 = After 1-5 weeks).

EFFICACY		Zeel®	Hyalart®
doctor	no.	55 patients	57 patients
	mean	57 mm	59 mm
	min.	0 mm	0 mm
	max.	96 mm	98 mm
patient	no.	55 patients	55 patients
	mean	59 mm	63 mm
	min.	0 mm	0 mm
	max.	97 mm	100 mm
TOLERABILITY			
doctor	no.	55 patients	57 patients
	mean	96 mm	95 mm
	min.	1 mm	12 mm
	max.	100 mm	100 mm
patient	no.	55 patients	55 patients
	mean	94 mm	97 mm
	min.	13 mm	36 mm
	max.	100 mm	100 mm

Final evaluation (efficacy / tolerability) by doctor and patient using the VAS scale (Efficacy: 0 mm = no improvement, 100 mm = maximum improvement; Tolerability: 0 mm = very poorly tolerated, 100 mm = very well tolerated).

3

AUTHORS: WEISER M., GEGENHEIMER L.H., KLEIN P.
TITLE: **A randomized equivalence trial comparing the efficacy and safety of Luffa comp.-Heel nasal spray with sodium cromoglycate spray in the treatment of seasonal allergic rhinitis.**
PUBLISHED IN: Research in Complementary Medicine, **1999/6.**
PUBLISHED IN ITALIAN: La Medicina Biologica, **2000/1; 3:11.**

- **TRIAL METHODOLOGY:** A controlled, multicentric, randomised, double-blind clinical trial.
The clinical trial meets the criteria of homogeneity, identifies a primary objective, and dimensions the sample in accordance with statistical criteria of reliability.

- **COUNTRY:** Germany - 17 clinics

- **NUMBER OF PATIENTS RECRUITED:** 146, resident in the same geographical area

- **DISEASE:** hay fever (evidenced by RAST with quantification of IgE).

- **TREATMENT:** patients
 - homeopathic group = Luffa comp.-Heel® = 72 patients
 - allopathic group = Sodium cromoglycate spray = 74 patients

- **DURATION OF THE TRIAL:** February to August (when hazel, birch, alder, ash, artemisia and rye pollens are present in the atmosphere)

- **DOSE:** 0.14 ml q.i.d. for both treatments

- **EVALUATION CRITERIA:** RQLQ (Rhinconjunctivitis Quality of Life Questionnaire) = 28 items relating to specific symptoms and their consequences on everyday life:
 - nasal symptoms (4 items)
 - eye symptoms (4 items)

- general symptoms (7 items)
- sleep disorders (3 items)
- problems associated with rhinoconjunctivitis (3 items)
- consequences on everyday life (3 items)
- neurological symptoms (4 items)

■ THERAPEUTIC EFFICACY:

(P = patient)
(M = doctor)

- | | |
|--------------------|---------------------------------------------------------------------------------------------------------------------|
| 1) excellent in | 13% of patients in the
allopathic group (vs 24%) = P
16% of patients in the
homeopathic group (vs 18%) = M |
| 2) good in | 63% of patients in the
allopathic group (vs 55%) = P
63% of patients in the
homeopathic group (vs 66%) = M |
| 3) satisfactory in | 18% of patients in the
allopathic group (vs 14%) = P
17% of patients in the
homeopathic group (vs 9%) = M |
| 4) poor in | 6% of patients in the
allopathic group (vs 6%) = P
4% of patients in the
homeopathic group (vs 6%) = M |

■ SIDE EFFECTS:

4 cases, all mild (stinging of the nasal mucosa and slight facial rash)

■ TOLERABILITY:

excellent + good = 94% (vs 97%) = P
excellent + good = 92% (vs 89%) = M

■ AUTHORS' CONCLUSIONS:

"The homeopathic nasal spray is as efficient and well tolerated as conventional therapy with sodium cromoglycate for the treatment of hay fever".

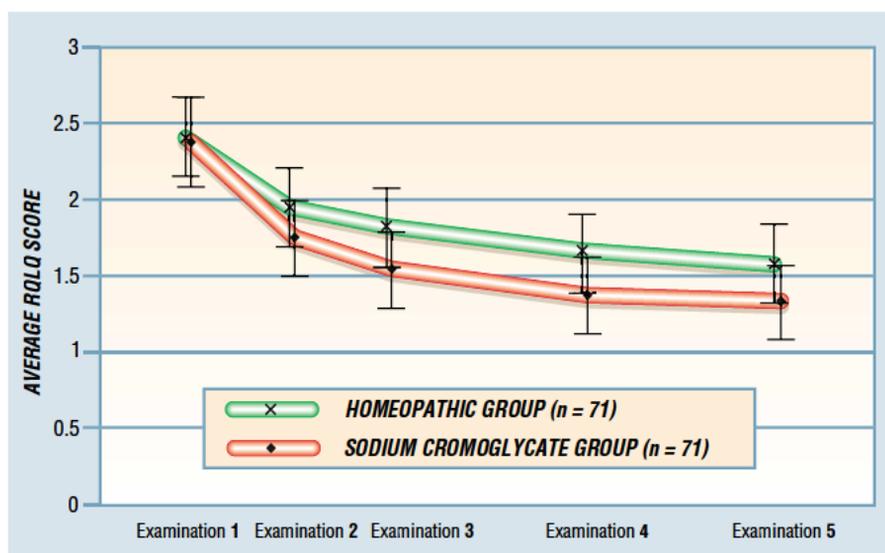
■ FINAL RESULT:

Luffa comp -Heel® is not inferior to sodium cromoglycate spray in the treatment of hay fever.

TOTAL COST:

homeopathic treatment € 27.90

allopathic treatment € 45.44



General RQLQ score for the two groups (from examination 1 to examination 5).

RQLQ PARAMETERS	EXAMINATION 1			EXAMINATION 5		
	Homeopathic group	Sodium cromoglycate group	Statistics P(X<Y) (95% CI LB)	Homeopathic group	Sodium cromoglycate group	Statistics P(X<Y) (95% CI LB)
• Nasal symptoms	3.07±1.31	3.25±1.51	0.53 (0.45)	1.86±1.42	1.70±1.34	0.47 (0.39)
• Eye symptoms	1.87±1.50	2.12±1.53	0.55 (0.46)	1.26±1.34	1.10±0.98	0.50 (0.42)
• Sundry symptoms	1.99±1.38	1.86±1.37	0.47 (0.38)	1.44±1.21	1.20±0.98	0.45 (0.37)
• Emotional symptoms	1.76±1.38	1.74±1.17	0.51 (0.42)	1.37±1.36	0.99±0.95	0.44 (0.36)
• Sleep disorders	1.65±1.29	1.53±1.39	0.46 (0.38)	1.24±1.18	1.08±1.06	0.47 (0.39)

Mean values ± SD of the RQLQ sub-scores at examination 1 and examination 5 [Mann-Whitney P(X<Y) less than 95% of confidence interval (in brackets)].

4

AUTHOR: WEISER M.
TITLE: **Homeopathic vs. conventional treatment of vertigo: a randomized double-blind controlled clinical study.**
PUBLISHED IN: Archives of Otolaryngology – Head and Neck Surgery (American Medical Association), **1998**, August.
PUBLISHED IN ITALIAN: La Medicina Biologica, **1999/1**; 43:44.

- **TRIAL METHODOLOGY:** A controlled, multicentric, randomised double-blind study.
The clinical trial meets the criteria of homogeneity, identifies a primary objective, and dimensions the sample in accordance with statistical criteria of reliability.

- **COUNTRY:** Germany - 15 clinics

- **NUMBER OF PATIENTS RECRUITED:** 119

- **DISEASE:**
 - acute and chronic forms of vertigo with various aetiologies (Menière’s syndrome)
 - vasomotor syndromes

- **TREATMENT:**
 - homeopathic group = Cocculus-Heel® = 53 patients
 - allopathic group = Betahistine = 52 patients

- **DURATION OF THE TRIAL:** 6 weeks

- **DOSE:**
 - Cocculus-Heel®: 15 drops t.i.d.
 - Betahistine (8 mg/ml): 15 drops t.i.d.

- **EVALUATION CRITERIA:**
 - 1) frequency, duration and intensity of vertigo attacks
 - 2) quality of life (questionnaire)
 - 3) specific symptoms associated with vertigo (questionnaire)
 - 4) global evaluation of efficacy

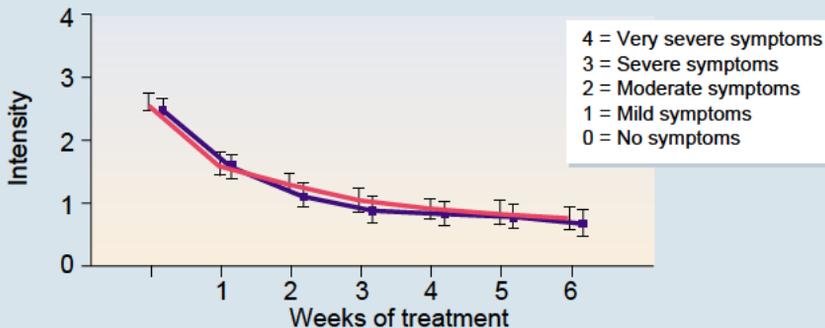
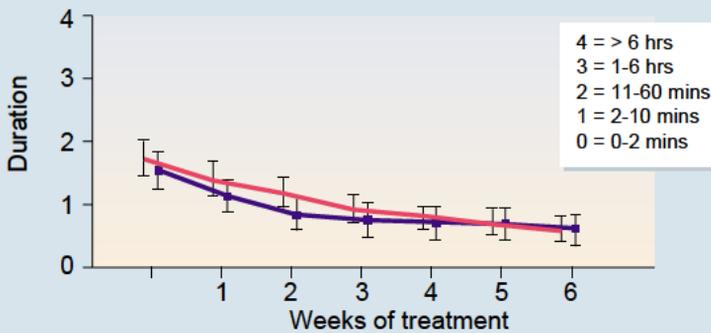
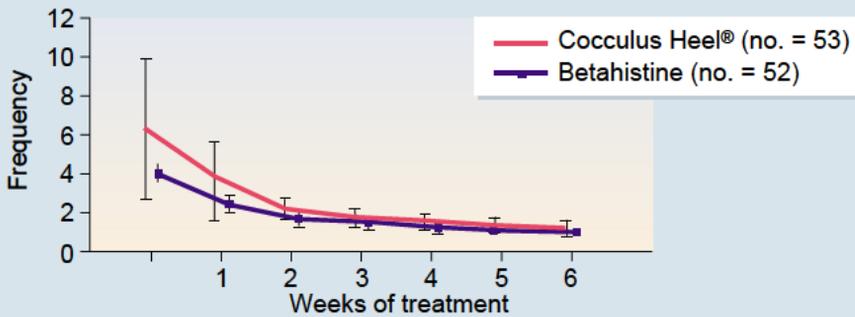
AUTHOR'S CONCLUSIONS:

"The data obtained demonstrate that the efficacy and tolerability of the homeopathic drug in treating forms of vertigo with various origins have been confirmed in a phase IV clinical trial."

FINAL RESULT:

Cocculus-Heel® is not inferior to betahistine in the treatment of forms of vertigo with different aetiologies.

TOTAL COST: homeopathic treatment € 65.10
 allopathic treatment € 70.70



Time course of symptoms in the two groups of patients.

5

AUTHOR: ARRIGHI A.
TITLE: **Evaluation of clinical efficacy in a homotoxicologic protocol for prevention of recurrent respiratory infections in pediatrics.**
PUBLISHED IN: La Medicina Biologica, 2000/3; 13:21.

- **TRIAL METHODOLOGY:** A controlled, monocentric clinical trial. The clinical trial meets the criteria of homogeneity, identifies a primary objective, and dimensions the sample in accordance with statistical criteria of reliability.

- **COUNTRY:** Italy – paediatric clinic.

- **NUMBER OF PATIENTS RECRUITED:** 212 paediatric cases

- **DISEASE:** Recurrent respiratory infections (RRI)

- **TREATMENT:**
 - **Homeopathic group** = Engystol® N + Lymphomyosot® + Echinacea comp. S = 68 patients (Group A)
 - **Allopathic group 1** = Polimod® (synthetic thymic peptide) + Biomunil® (ribosomal fractions, Klebsiella membrane fraction) = 65 patients (Group B)
 - **Allopathic group 2** = Sundry treatments (antibiotics, antipyretics, vitamins) = 79 patients (Group C)

- **INCLUSION CRITERIA:** positive history of RRI (at least 6 RRI episodes in the equivalent period of the preceding year)

- **DURATION OF THE TRIAL:** 60 days (November + December)

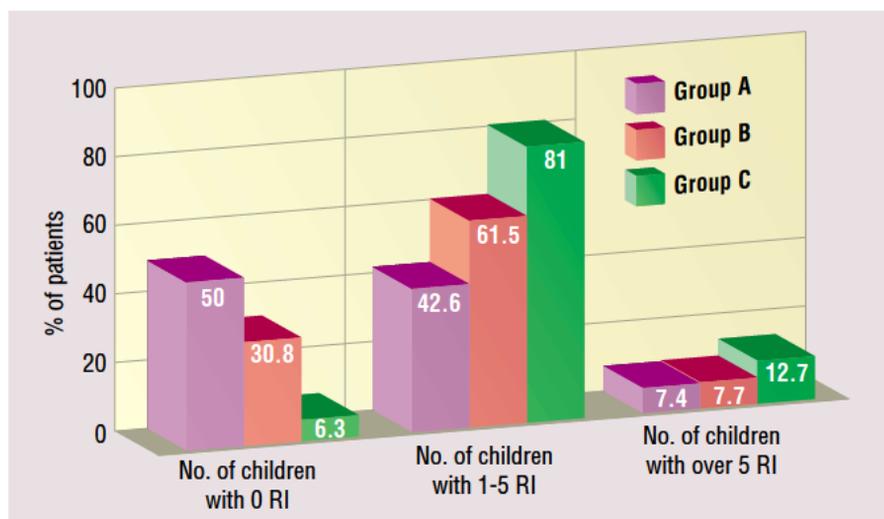
<p>■ DOSE:</p> <p>months)</p>	<p>1) homeopathic protocol:</p> <ul style="list-style-type: none"> - Engystol® N tablets (1 tablet every morning for 20 consecutive days a month for 3 consecutive - Lymphomyosot® drops (10 drops b.i.d. for 3 consecutive months) - Echinacea comp. S ampoules (2 ampoules per os a week for 3 consecutive months). <p>2) allopathic protocol:</p> <ul style="list-style-type: none"> - Polimod® oral vials (1 vial/day for 3 consecutive months) - Biomunil® sachets (1 sachet/day 4 days a week for 3 consecutive weeks, followed by 1 sachet on 4 days a month for the next 3 months)
<p>■ EVALUATION CRITERIA:</p>	<ul style="list-style-type: none"> - number of episodes of respiratory infections - total number of days of fever - use of antibiotic
<p>■ THERAPEUTIC EFFICACY:</p>	<ul style="list-style-type: none"> 1 to 5 episodes of RRI: - 42.6% of patients in the homeopathic group (Group A) - 61.5% of patients in the allopathic reference group (Group B) - 81% of patients in the group treated with "other" allopathic drugs (sundry treatments) (Group C) excluding antibiotics administered for long periods
<p>■ AUTHOR'S CONCLUSIONS:</p>	<p><i>"The absence of side effects and good compliance with the protocol make homotoxicological treatment suitable for large-scale use".</i></p>
<p>■ FINAL RESULT:</p>	<p>the homeopathic product proved superior to the corresponding allopathic reference protocol.</p>

TOTAL COST:	homeopathic treatment € 99.80
	allopathic treatment € 239.28
	(allopathic group 1)

120-DAY FOLLOW-UP NUMBER OF RESPIRATORY INFECTIONS			
	Group A	Group B	Group C
No. of children with 0 episodes of RI in 120 days	34 (50%) §	20 (30.8%) §	5 (6.3%)
No. of children with 1-5 episodes of RI in 120 days	29 (42.6%) §	40 (61.5%)	64 (81%)
No. of children with over 5 episodes of RI in 120 days	5 (7.4%)	5 (7.7%) §	10 (12.7%)

Number of respiratory infections in the 3 groups.

§ = the group treated is significantly different from the placebo group

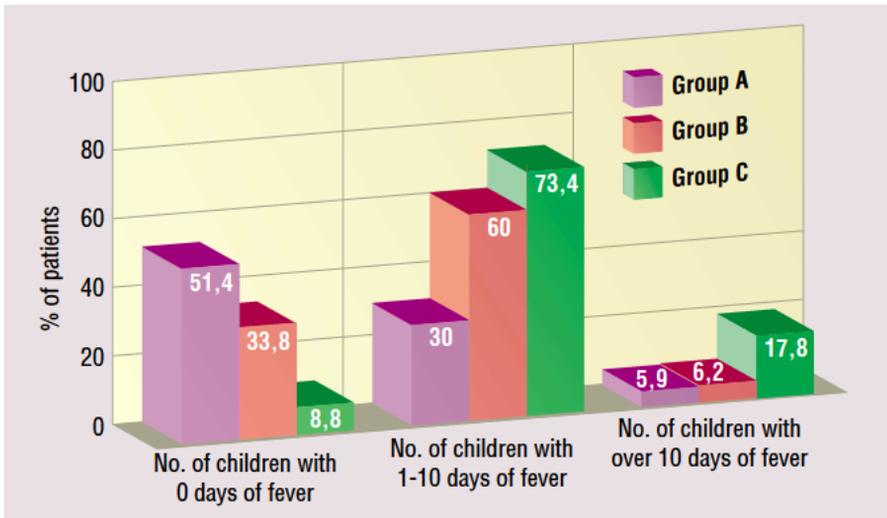


Graphic representation of the above table.

120-DAY FOLLOW-UP NUMBER OF DAYS OF FEVER			
	Group A	Group B	Group C
No. of children with 0 days of fever in 120 days	35 (51.4%) §	22 (33.8%) §	7 (8.8%)
No. of children with 1-10 days of fever in 120 days	19 (30%) §	39 (60%)	58 (73.4%)
No. of children with over 10 days of fever in 120 days	4 (5.9%)	5 (6.2%) §	4 (17.8%)

Number of days of fever in the 3 groups.

§ = the group treated is significantly different from the placebo group

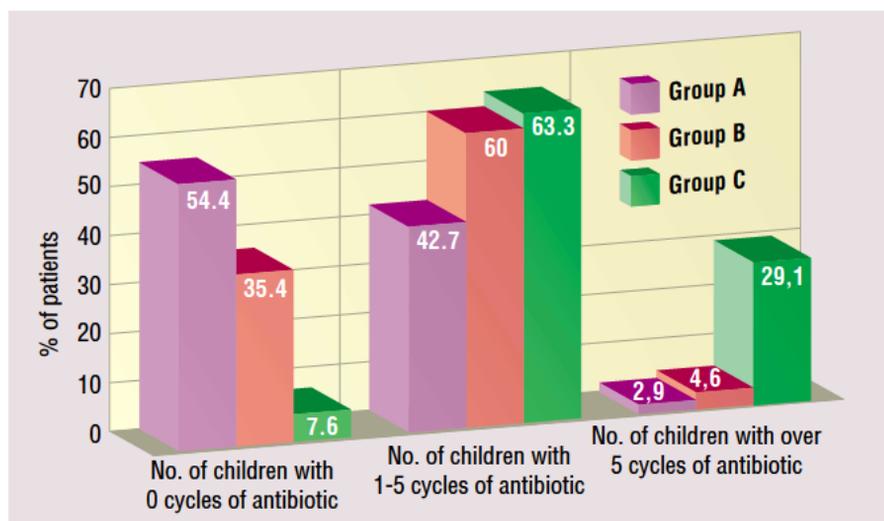


Graphic representation of the above table.

120-DAY FOLLOW-UP USE OF ANTIBIOTIC			
	Group A	Group B	Group C
No. of children not treated with antibiotics in 120 days	37 (54.4%) §	23 (35.4%) §	6 (7.6%)
No. of children treated with 1-5 cycles of antibiotic in 120 days	29 (42.7%)	39 (60%)	50 (63.3%)
No. of children treated with over 5 cycles of antibiotic in 120 days	2 (2.9%) §	3 (4.6%) §	23 (29.1%)

Use of antibiotics in the 3 groups.

§ = the group treated is significantly different from the placebo group



Graphic representation of the above table.

6

AUTHORS: MARONNA U., WEISER M., KLEIN P.
TITLE: **Oral treatment of osteoarthritis of the knee with Zeel S tablets.**
PUBLISHED IN: Orthopädische Praxis, **2000**, 5. La Medicina Biologica, **1999**/4; 74. Abstract

- **TRIAL METHODOLOGY:** Controlled, multicentric, randomised, double-blind clinical trial. The clinical trial meets the criteria of homogeneity, identifies a primary objective, and dimensions the sample in accordance with statistical criteria of reliability.

- **COUNTRY:** Germany

- **NUMBER OF PATIENTS RECRUITED:** 104

- **DISEASE:** osteoarthritis

- **TREATMENT:**  **Homeopathic group** = Zeel® comp. = 53 patients (26 M, 27 F) ■
Allopathic group = Diclofenac = 51 patients (26 M, 25 F)

- **DURATION OF THE TRIAL:** 10 weeks

- **DOSE:** Zeel® comp. 1 tablet t.i.d. vs Diclofenac 1 x 25 mg tablet t.i.d.

- **EVALUATION CRITERIA:** **1) EFFICACY**
 - the WOMAC (Western Ontario Mac Master) arthritis index (a widely used reference index for the evaluation of osteoarthritis)

2) TOLERABILITY

- final therapeutic evaluation by doctor and patient
- side effects
- vital parameters
- laboratory tests.

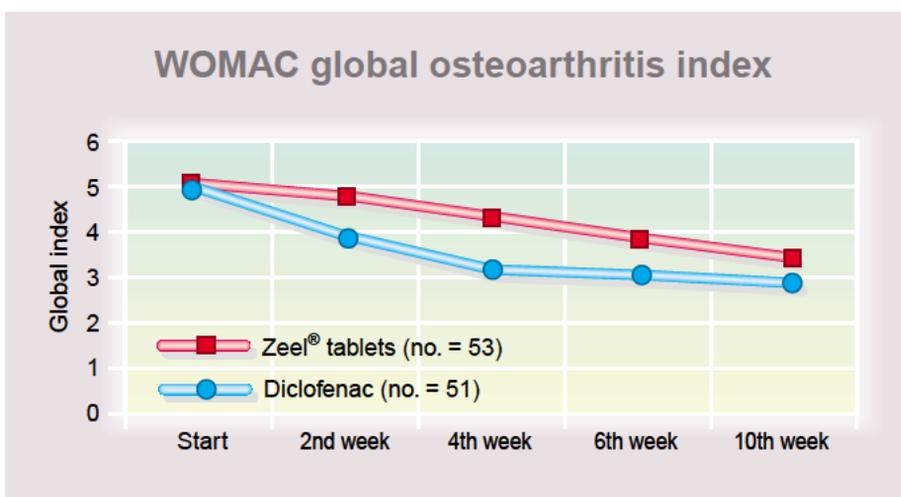
AUTHORS' CONCLUSIONS:

"This controlled clinical trial demonstrates that the efficacy of Zeel® comp., in the treatment of mild to moderate osteoarthritis of the knee is equivalent to that of diclofenac. The trial also confirms the therapeutic safety of Zeel® tablets".

FINAL RESULT:

Zeel® comp. tablets are not inferior to diclofenac in the treatment of osteoarthritis.

TOTAL COST: homeopathic treatment € 44.00
 allopathic treatment € 86.73



Trend of WOMAC global osteoarthritis index in the two groups compared.

7

AUTHOR: BONONI M.
TITLE: **Echinacea comp. Forte S in the prophylaxis of post-operative infections. A comparative study versus ceftazidime and ceftriaxone.**
PUBLISHED IN: La Medicina Biologica, **2001/1**; 17:22.

- **TRIAL METHODOLOGY:** A controlled, monocentric, randomised clinical trial.
The clinical trial meets the criteria of homogeneity, identifies a primary objective, and dimensions the sample in accordance with statistical criteria of reliability.

- **COUNTRY:** Italy: 1st Pathological Surgery Division, La Sapienza University, Rome

- **NUMBER OF PATIENTS RECRUITED:** 90 patients (breast cancer, laparocoele, inguinal hernia, gallstones, prostate adenomyomatosis, uterine fibromatosis, follicular goitre and varicose veins).

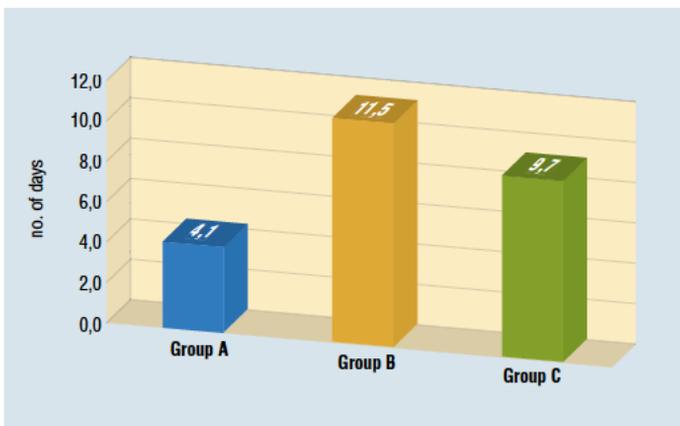
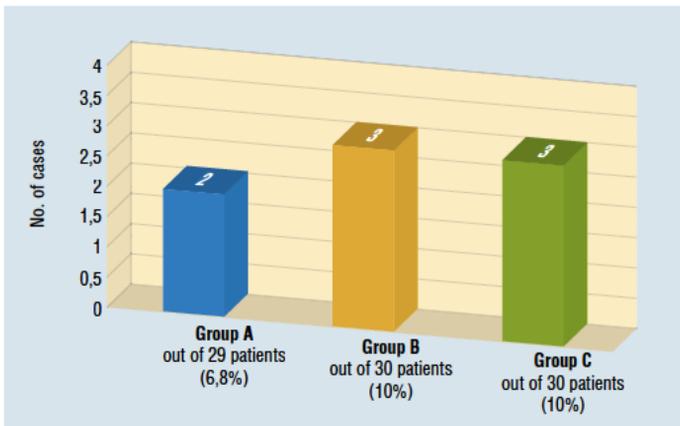
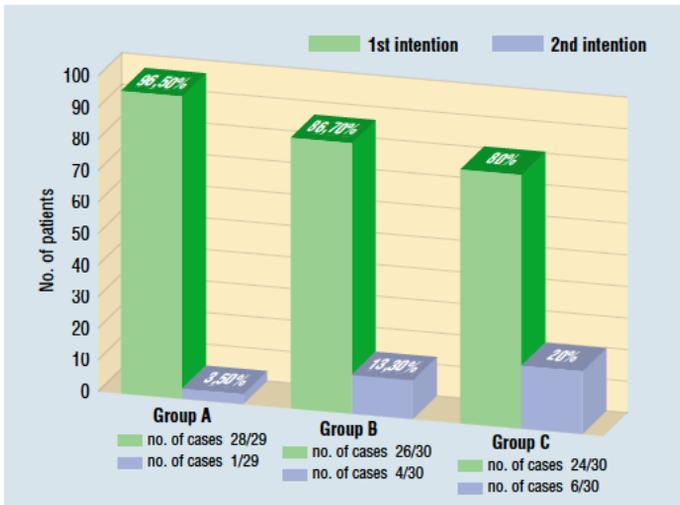
- **DISEASE:** post-operative prophylaxis

- **TREATMENT:**
 - Homeopathic group =** Echinacea Compositum Forte S –Heel ampoules = 30 patients.
(1 ampoule the day before the operation; 1 ampoule on induction of anaesthesia; 1 ampoule on the 2nd and 4th day after the operation)
 - Allopathic group 1** Ceftazidime = 30 patients
1 g i.v. 2 hours before and at the end of the operation, and every 12 hours in the next 48 hours
 - Allopathic group 2** Ceftriaxone = 30 patients
2 g i.v. 2 hours before and at the end of the operation, and every 24 hours in the next 48 hours

- **DURATION OF THE TRIAL:** up to 15 days

■ DOSE:	<p>Homeopathic group = Echinacea Compositum Forte S –Heel = 1 ampoule the day before the operation; 1 ampoule on induction of anaesthesia; 1 ampoule on the 2nd and 4th days after the operation)</p> <p>Allopathic group 1 Cefotaxime = 1 g i.v. 2 hours before and at the end of the operation, and every 12 hours in the next 48 hours</p> <p>Allopathic group 2 Ceftriaxone = 2 g i.v. 2 hours before and at the end of the operation, and every 24 hours in the next 48 hours</p>
■ EVALUATION CRITERIA:	<ol style="list-style-type: none">1) variation in skin temperature2) variations in leucocyte concentrations3) wound healing (1st intention, 2nd intention)4) onset of infection5) duration of treatment6) duration of hospitalisation7) basic disorder8) associated therapeutic procedures
■ AUTHOR'S CONCLUSIONS:	<p><i>“The homeopathic treatment protocol used demonstrated tolerability and manageability, together with a high capacity to protect against post-operative infections. Biological antisepsis responds to the principles of health protection more effectively because it is physiological, devoid of toxic effects and therefore of better quality.”</i></p>
■ FINAL RESULT:	<p>the homeopathic protocol was not inferior to the two allopathic protocols in preventing post-operative infections.</p>

	homeopathic treatment € 20.70
TOTAL COST:	allopathic treatment 1 € 126.42
	allopathic treatment 2 € 159.68





AUTHORS: STAM C., BONNET M.S., VAN HASELEN R.A.
TITLE: **The efficacy and safety of a homeopathic gel in the treatment of acute low back pain: a multi-centre, randomised, double-blind comparative clinical trial.**
PUBLISHED IN: British Homeopathic Journal, 2001/90, 21-28

- **TRIAL METHODOLOGY:** Controlled, multicentric, randomised, double-blind trial.
The clinical trial meets the criteria of homogeneity, identifies a primary objective, and dimensions the sample in accordance with statistical criteria of reliability.

- **COUNTRY:** U.K: Bristol and Manchester; general practitioners clinics

- **NUMBER OF PATIENTS RECRUITED:** 161

- **DISEASE:** acute low back pain

- **TREATMENT:** 
 - **Homeopathic group** Spiroflor SRL, gel = 83 patients
 - **Non-homeopathic group** Cremor Capsici Compositum FNA, ointment = 78 patients

- **EVALUATION CRITERIA:** with The trial evaluated pain reduction in accordance with a visual analog scale. In particular the trial was designed to demonstrate any adverse events (AEs) or adverse drug reactions (ADRs). The patients recruited were asked to record in a diary the intensity of pain, quality of sleep at night, and use of paracetamol to alleviate the pain.

- **DURATION OF THE TRIAL:** 1 week

- **DOSE:** 3 g t.i.d. for both treatments

- **INCLUSION CRITERIA:** age, acute pain in the last 72 hours, lack of lumbar pain in the preceding 3 months, limited movement (doctor's evaluation)

- **EXCLUSION CRITERIA:** radicular symptoms, location of irradiated pain above T12, rheumatoid arthritis, ankylosing spondylitis, confirmed hypersensitivity to a constituent, use of drugs with the exception of paracetamol, use of other treatments for acute pain, pregnancy, over 96 hours had elapsed from start of pain, including discontinuance of analgesics and/or NSAIDs.
- **THERAPEUTIC EFFICACY:** the two drugs proved to be equivalent.
- **SIDE EFFECTS:** AEs (Adverse Events)
 Homeopathic group: 11%
 Allopathic group: 26%
 ADRs (Adverse Drug Reactions), patients who had to discontinue the treatment:
 Homeopathic group: 0%
 Allopathic group: 24%, 4 of which were serious.
 11% had to discontinue the treatment.
- **FINAL RESULT:** the drugs tested are equally effective in the treatment of acute low back pain, but the homeopathic drug is better tolerated and less likely to produce adverse effects.

TOTAL COST: homeopathic treatment € 2.79
 allopathic treatment € 7.64

RESULTS	SRL	CCC
Excellent	7,7	8,3
Good	37,2	54,3
Fair	32,1	13,9
Poor	12,8	19,4
Nil	9,0	2,8
Worse	1,3	1,4

**Clinical results (% frequency)
 in the doctor's opinion.**

RESULTS	SRL	CCC
Excellent	6,5	4,2
Good	35,1	47,9
Fair	29,9	22,5
Poor	16,9	16,9
Nil	10,4	2,8
Worse	1,3	5,6

**Clinical results (% frequency)
 in the patient's opinion.**

9

AUTHORS: KÜSTERMANN R.W., WEISER M., KLEIN P.
TITLE: **Antihomotoxic treatment of conjunctivitis. Results of a prospective, controlled, cohort study.**
PUBLISHED IN: Biologische Medizin, **2001**, 3.
PUBLISHED IN ITALIAN: La Medicina Biologica, **2002/1**; 3-9.

- **TRIAL METHODOLOGY:** Controlled multicentric clinical trial. The clinical trial meets the criteria of homogeneity, identifies a primary objective, and dimensions the sample in accordance with statistical criteria of reliability.

- **COUNTRY:** Germany

- **NUMBER OF PATIENTS RECRUITED:** 769

- **DISEASE:**
 - conjunctivitis (acute, chronic and periodic)
 - allergic conjunctivitis
 - marginal blepharitis

- **SYMPTOMS CONSIDERED:**
 - pain, stinging and itching
 - hypersensitivity and swelling
 - watering eyes, sensation of foreign body in the eye, sharp retrobulbar pain

- **TREATMENT:**
 - **Homeopathic group** = Euphrasia-Heel® single-dose eyedrops = 456 patients
 - **Allopathic group** = Tetryzoline 0.5 mg single-dose eyedrops = 313 patients

- **DOSE:**
 - Euphrasia-Heel® (0.45 mg): 1 single dose t.i.d.
 - Tetryzoline (0.5 mg): 1 single dose t.i.d.

- **DURATION OF THE TRIAL:** 2 weeks

- **EVALUATION CRITERIA:**
 - very good (symptoms completely disappeared)
 - good (significant improvement)
 - moderate (slight improvement)
 - no improvement
 - symptoms worsened

- **MEAN DURATION OF TREATMENT:**
 - Euphrasia-Heel® group: 12.5 days
 - Tetryzoline group: 15.9 days

- **THERAPEUTIC EFFICACY:**
 - very good + good = 88% Euphrasia-Heel® group
 - very good + good = 95% Tetryzoline group

- **TOLERABILITY:**
 - very good + good = 98% Euphrasia-Heel® group
 - very good + good = 100% Tetryzoline group

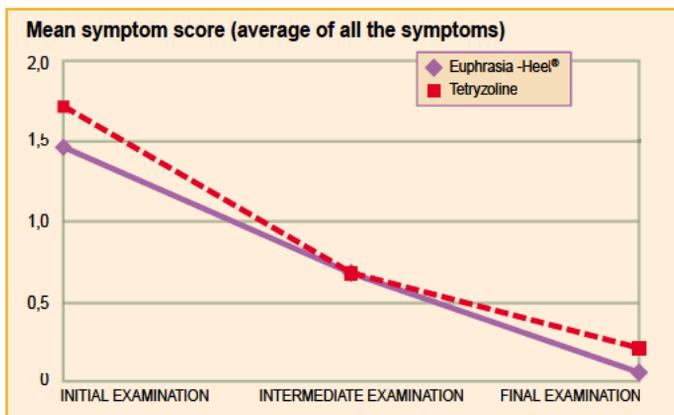
- **AUTHORS' CONCLUSIONS:**

"The statistical analysis demonstrates that the efficacy of Euphrasia-Heel® single-dose drops is equivalent to that of tetryzoline in the treatment of conjunctivitis and blepharitis, with a better effect on the symptoms "pain" and "stinging" of the eyes. As the therapeutic equivalence of Euphrasia-Heel® has been demonstrated, this drug can be considered a good, safe homeopathic alternative for the treatment of conjunctivitis."

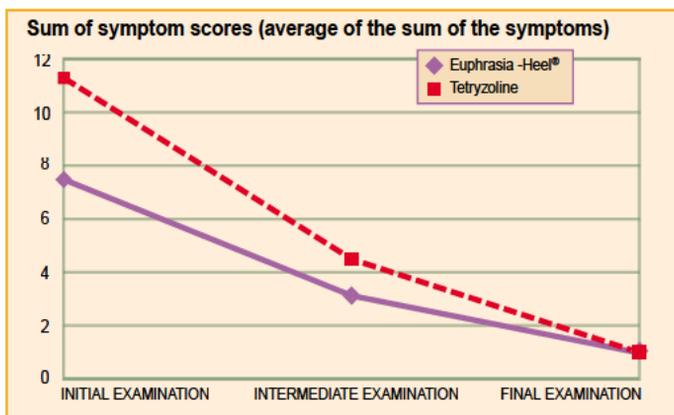
- **FINAL RESULT:**

Euphrasia-Heel® is not inferior to tetryzoline in the treatment of conjunctivitis.

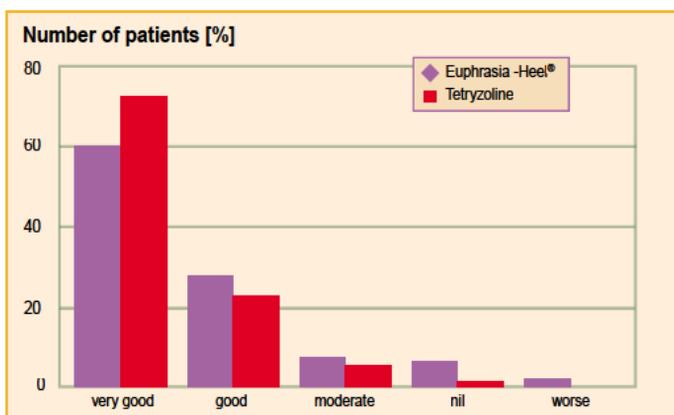
TOTAL COST:	homeopathic treatment	€ 8.00
	allopathic treatment	€ 8.52



Variation in mean symptom score at different times. Score range: none = 0, mild = 1, moderate = 2.



Variation of the sum of symptom scores at different times.



Global evaluation of efficacy of treatment by doctors.

10

AUTHORS: WOLSCHNER U., STRÖSSER W., WEISER M., KLEIN P.
TITLE: **Vertigo therapy: Cocculus -Heel® versus Dimenhydrinate.**
PUBLISHED IN: Biologische Medizin, **2001**, 4.
PUBLISHED IN ITALIAN: La Medicina Biologica, **2002/1**; 15-20.

- **TRIAL METHODOLOGY:** Controlled, multicentric, randomised clinical trial.
The clinical trial meets the criteria of homogeneity, identifies a primary objective, and dimensions the sample in accordance with statistical criteria of reliability.

- **COUNTRY:** Germany. Doctors recruited: 159 (GPs and ENT specialists)

- **NUMBER OF PATIENTS RECRUITED:** 774

- **DISEASE:** vestibular and non-vestibular vertigo

- **TREATMENT:** 
 - Homeopathic group** = Cocculus-Heel® = 352 patients
 - Allopathic group** = Dimenhydrinate = 422 patients

- **DURATION OF THE TRIAL:** up to 8 weeks (checks performed 2 and 4 weeks after the start)
Mean duration in both groups = 53 days.

- **DOSE:**
 - Cocculus-Heel®: 2-3 tablets t.i.d.
 - Dimenhydrinate: 50 mg (1 tablet) b.i.d./t.i.d.

- **EVALUATION CRITERIA:**
 - 1) number of attacks/day
 - 2) intensity of attacks
 - 3) duration of attacks
 - 4) associated symptoms (nausea, vomiting, perspiration)

- **THERAPEUTIC EFFICACY:**
(data reported by patients)
 - Homeopathic group**
 - Number of attacks/day: from 5.2 to 1
 - Intensity: moderate/severe to none/slight
 - Mean duration of each attack: from 2.5 min to < 1 min
 - Improvement after 1 week's treatment = 49%
 - Allopathic group**
 - Number of attacks/day: from 5.1 to 1
 - Intensity: moderate/severe to none/slight
 - Mean duration of each attack: from 2.5 min to < 1 min
 - Improvement after 1 week's treatment = 59%

- **OVERALL EFFICACY:**
(doctor's evaluation)
 - Homeopathic group:** = 88%
 - Allopathic group:** = 87%

- **COMPLIANCE WITH TREATMENT:**
 - Homeopathic group:** = 96%
 - Allopathic group:** = 93%

- **TOLERABILITY:**
(doctor's evaluation)
 - Homeopathic group:** = 99%
 - Allopathic group:** = 98%

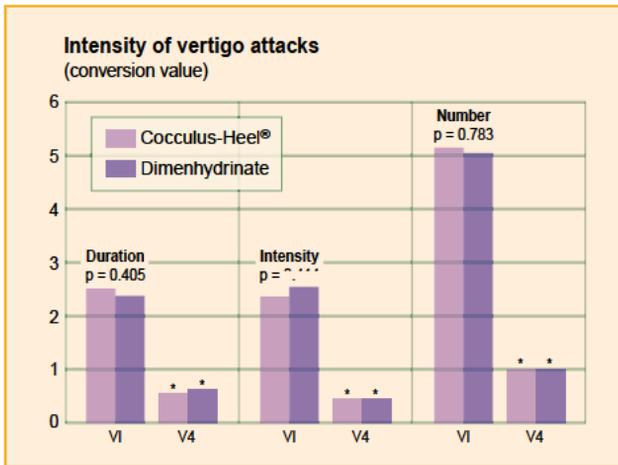
- **AUTHORS' CONCLUSIONS:**

"... in conclusion, this multicentric controlled trial confirms that Cocculus-Heel® is a safe, effective homeopathic treatment option for vertigo of differing aetiologies, and is not inferior in therapeutic terms to allopathic drugs containing dimenhydrinate."

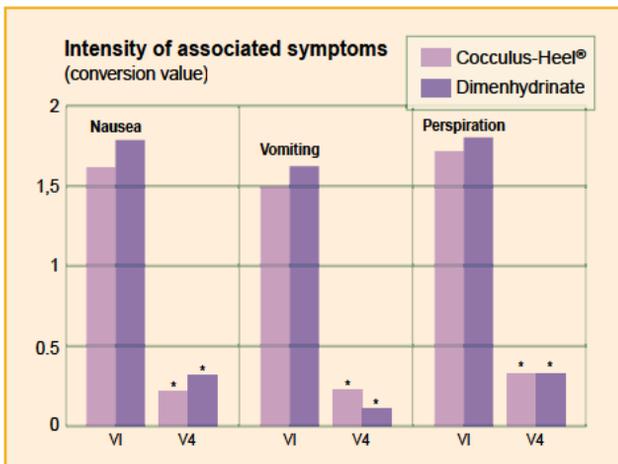
- **FINAL RESULT:**

Cocculus-Heel® is not inferior to dimenhydrinate in the treatment of forms of vertigo with various aetiologies.

TOTAL COST: **homeopathic treatment € 49.60**
 allopathic treatment € 18.63 to € 106.00



Modifications in daily duration, intensity and number of vertigo attacks (VI = initial examination; V4 = final examination (after max. 8 weeks); the values of p at VI demonstrate a homogeneous situation; level of intensity of associated symptoms; * p < 0.001, comparison between VI and V4.



Modifications in mean intensity of associated symptoms: nausea, vomiting and perspiration (VI = initial examination; V4 = final examination (after max. 8 weeks); value 0 = no symptoms; 1 = mild; 2 = moderate; * p < 0.001, comparison between VI and V4

CONCLUSIONS

Until recently, it was often said that homeopathy cannot be considered a valid treatment because of the lack of scientific data.

The impossibility of supplying scientific data seemed to be due to the very nature of the discipline founded by C.F.S. Hahnemann, firstly because it uses medicines at such low dilutions that they are sometimes actually undetectable, and secondly because of the customised nature of homeopathic treatment, which was alleged to make it impossible to apply standard protocols.

As homeopathic medicine is based on different paradigms from conventional medicine, the very concepts of health and disease differ considerably between the two approaches, and the view of man as a holistic unit is exclusively held by practitioners of homeopathic medicine, it might seem impossible to define standard clinical protocols.

However, thanks to the efforts of independent researchers, some major studies demonstrate that homeopathic protocols can perfectly fit the methodological standards used in conventional medicine and be published in prestigious international journals.

In nosologically defined disorders, in which *“personalisation”* of symptoms is limited, experimental clinical research protocols can also be applied to evaluate the efficacy of the most appropriate homeopathic medicines.

Numerous experimental studies have been conducted on this basis, and their methodological level has progressively improved over the years.

Nevertheless, most of the members of the medical profession and the media have failed to perceive the existence of this body of studies, which demonstrate the therapeutic efficacy of homeopathic medicines.

The aim of the present volume was to fill this lack of information by a compendium made of some of the latest and most significant literature in the field.

Very briefly, a large body of studies demonstrates that the efficacy of homeopathic medicines is not due to the “mythical” placebo effect, thus finally dispelling a series of superficial, prejudiced attitudes.

Among these, a set of studies compare homeopathic vs allopathic medicines. These trials were conducted in accordance with Helsinki Declaration on the therapeutic efficacy.

Most of the best studies relate to the branch of homeopathy known as homotoxicology which, with its pragmatic attitude and rejection of therapeutic extremism, seems to meet current demand for integrated medicine most effectively.

These studies demonstrate that the effect of homeopathic medicines may be at least similar to that of the allopathic reference drug used for the same disorder. They also confirm that homeopathic medicines, unlike allopathic drugs, rarely produce side effects. Finally, they show that homeopathic remedies are usually cheaper, and in some cases much cheaper, than the corresponding conventional treatment.

Everybody is entitled to his own opinion and can deny the evidence, even when faced with the clearest proof. But who hold public and institutional offices and responsibilities have the duty to analyse actively all the body of information that may improve the patient’s quality of life.

We hope that widespread circulation of this book will enable an increasing number of people to form an objective opinion about homeopathy, which has been so controversial for many years. We also hope that the consequent awareness of those who hold international, national and local responsibilities in the health field will lead to substantial improvements in the health of the population in the near future.

It may seem paradoxical that tiny amounts of an active constituent (diluted by the very special process of homeopathic production) can produce effects on living beings, but this is evidently a scientific fact.

Science acts on the basis of objective, verifiable observations; if the event demonstrated cannot be interpreted by a theory, it is the theory that needs to be revised. This is the principle behind the progress of science.

We trust that subjective opinions will leave room for the objective findings of laboratories and clinical research centres, so that full medical integration can be achieved, without losing the specific identity of different therapeutic approaches, as this would be the most appropriate prelude to the new medicine of the third millennium.

This volume was produced jointly by A.I.O.T. and Guna S.r.l.

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A.I.O.T. (Italian Homotoxicology Medical Association) was founded in Milan in 1983. Its large membership (over 4,000 doctors in 2001) makes it one of the most important medical associations in Italy, and by far the largest in the field of non-conventional medicine.

AIOT's activities focus on training courses for doctors, involving intensive teaching activities conducted all over Italy. Every year some 500 training courses are held on the various branches of non-conventional medicine, some in liaison with numerous Medical Councils and leading Italian Universities.

They are organised such as long-term courses (i.e. the three-year course in Homeopathy, Homotoxicology and Integrated Disciplines, the three-year course in Osteopathy and Global Manual Therapy, the one-year School of Complementary Dental Disciplines and others) or as two-day training seminars in various subjects related with non-conventional medicine.

In AIOT courses, doctors learn homeopathy and the main branches of non-conventional medicine, which are interpreted and taught according to the modern discoveries in the field of enzymology, molecular biology, immunology and PNEI (psychoneuroendocrine immunology).

The lecturers are leading academics and doctors who are particularly expert in their own fields.

Special emphasis is given to homotoxicology, a modern branch of the German school of homeopathy.

The teaching is supported by numerous publications.

The association's official organ is "La Medicina Biologica" (Biological Medicine), founded in 1983, the first Italian medical journal devoted to homeopathy and non-conventional medicine. The journal, which features original research and clinical papers and various monographic supplements, has over 25,000 Italian doctors readers.



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Guna srl, founded in 1983, is now Italy's leading company in the field of homeopathic medicines. The company's mission, in accordance with ethical principles, is the production and distribution of high-quality, innovative, ecological remedies of proven efficacy.

In addition to the production of its own range of homeopathic medicines developed in its laboratory on the basis of modern immunology and state-of-the-art homeopathy, Guna is the sole Italian distributor of various manufacturers, especially the German companies -Heel (one of the largest homeopathic companies in Germany) and Staufen Pharma (the most prestigious manufacturer of homeopathic nosodes), French manufacturer Abbé Chaupitre (the oldest homeopathic laboratory in Europe), and the British Bach Flower Company.

In the field of natural medicine, Guna also distributes Symbiopharm (the company that invented microbiological therapy and the first probiotic products), AR_D antioxidants (a range of diet products with specific anti free-radicals activity), SON Formula (essential amino-acids) and VIT Formula (a complex of vitamins, mineral salts and trace elements).

The constant search for the best in the field of therapeutic innovation, together with particular care for social issues, has led Guna to cooperate with international fair trade centres, in order to distribute the best products in the phytotherapy tradition of the third world countries through the "Pharmacy Fair Trade" program.

The company also has a publishing division (Guna Editore), which focuses on the most significant new acknowledgements in the field of non conventional medicine.

The Guna Editore catalogue includes over 40 titles by leading European authors.

Guna also promotes numerous projects designed to popularise biological medicine, invests heavily in R&D, and supports numerous associations that specialise in training doctors and pharmacists.

*“Homeopathy is the latest
and most refined method of treating
patients economically
and non-violently.*

*Government must encourage
and patronise it in our country.
Late Dr Hahnemann was a man
of superior intellectual nerve
and a means of vast saving
of human life.*

*I bow before his skill
and the Herculean
and humanitarian labour he did.”*

*Mahatma Gandhi
30/8/1936*

