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).

Table 1
Total number of scientific publications reporting significant results:

homeopathic medicine ***superior*** *to placebo: 77*

homeopathic medicine ***not inferior***

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
INTERNATIONAL SCIENTIFIC JOURNAL:	**INTERNATIONAL SCIENTIFIC JOURNAL:**
• LANCET	• CANCER
• BRITISH MEDICAL JOURNAL	• THROMBOSIS RESEARCH
• RHEUMATOLOGY	• JOURNAL OF CLINICAL PHARMACOLOGY
• PHLEBOLOGY	• ARCHIVES OF OTOLARINGOLOGY/ HEAD AND NECK SURGERY
• PEDIATRICS	• ARZNEIMITTEL FORSCHUNG/DRUG RESEARCH
• 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	
NATIONAL SCIENTIFIC JOURNAL	
• 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.	*Fortsch. Med.*, **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.	*Arzneim. Forsch./Drug Res.*, **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.	*Br. Hom. J.*, **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.	*Lancet*, **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.	*Allergologie*, **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.	*Phytomedicine*, **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.	*British Medical Journal* **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.	*Am. Rev. Resp. Dis.*, **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?	*Lancet*, **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.	*Research in Complementary Medicine*, **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.	*Biologische Medizin*, **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.	*Allg. Hom. Zeitung*, **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.	*Br. J. Clin. Pharmac.*, **1978**; 6: 391-395.	The homeopathic medicine proved therapeutically superior
Rheumatoid arthritis	W.W. Gibson R.G., Gibson S.L.M., Mc Neil A.D,	Homeopathic therapy in rheumatoid arthritis: evaluation by double-blind clinical therapeutic trial.	*Br. J. Clin. Pharmac.*, **1980**; 9: 453-459.	The homeopathic medicine proved therapeutically superior
Rheumatoid arthritis	W.W. Wiesenauer M., Gaus W.	Demonstration of efficacy of a homeopathic medicine in chronic polyarthritis. Randomised double-blind trial.	*Akt Rheumatol.*, **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.	*Forts. der Med.*, **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).	*Brit. Med. J.*, **1989**, 299: 365-366.	The homeopathic medicine proved therapeutically superior
Trauma	Belon P. Gibson J., Haslam Y., Laurenson L., Newman P.,	Double blind trial of Arnica in acute trauma patients.	*Homoeopathy*, **1991**, 41: 54-55.	The homeopathic medicine proved therapeutically superior
Haemarthrosis	Robins M. Thiel W., Borho B.	The treatment of recent traumatic blood effusions of the knee joint.	*Biol. Medizin*, **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.	*Orthopädische Praxis*, **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.	*Orthopädische Praxis*, **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.	*Rheumatology (Oxford)*, **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.	*Université Paris Nord (Thesis),* **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.	*Cahiers Biother.*, **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.	*Phlebology*, **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.	*Br. Hom. J.*, **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.	*Br. Hom. J.*, **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.	*Thrombosis Res.*, **1987**, 48: 501-504.	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug

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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.	*J. Am. Inst. Homeopathy,* **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.	*Br. Homeopath. J.*, **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.	*Allg. Hom. Zeitung*, **1980**, 225: 22-28.	The homeopathic medicine proved therapeutically superior
Burns	Leaman A.M., Gorman D.	Cantharis in the early treatment of minor burns.	*Arch. Emerg. Med.*, **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.	*Proc. 45th LMHI Congr., Barcelona, Spain*, **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.	*Ca. Med. Assoc. J.*, **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.	*Allg. Hom. Zeitung*, **1973**; 218: 111-121.	The homeopathic medicine proved therapeutically superior
Gastritis	Ritter H.	Double-blind homeotherapeutic study and the issues involved.	*Hippokrates*, **1966**, 12: 472-476.	The homeopathic medicine proved therapeutically superior
Irritable colon	Rahlfs V.W., Mossinger P.	Asa foetida in the treatment of irritable colon: double-blind clinical trial.	*Dtsch. Med. Wschr.*, **1979**, 104: 140-143.	The homeopathic medicine proved therapeutically superior
Cholecystitis	Mossinger P.	Homeopathy and naturopathy. How to overcome conflicts.	*Hippokrates (Stuttgart)*, **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.	*Berl. J. Res. Hom.*, **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.	*Br. Hom. J.*, **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.	*Pediatrics*, **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.	*J. Altern. Complement. Med.*, **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 toxaemia of pregnancy.	*B.T.*, **2000**, 4 (Ukrainian edition)	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug

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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.	*Université de Bordeaux (Thesis),* **1983**.	The homeopathic medicine proved therapeutically superior
Leucorrhoea	Carey H.	Double blind clinical trial of Borax and Candida in the treatment of vaginal discharge.	*Comm. Br. Hom. Res. Grp.,* **1986** 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.	*Rev. Fr. Gynecol. Obstét.,* **1995**, 90: 94-95.	The homeopathic medicine proved therapeutically superior
Childbirth (pain)	Coudert M.	Experimental study of the action of Caulophyllum in false labour.	*Université de Limoges (Thesis),* **1981**.	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.	*Cahiers de Biothérapie,* **1987**, 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.	*Proc. V Congr. O.M.H.I., Paris,* **1994**.	The homeopathic medicine proved therapeutically superior
Florid condylomatosis	Destro Castaniti M.	The use of Transfactor 11 in HPV infections (160 cases).	*La Medicina Biologica,* **2000**, 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.	*La Medicina Biologica*, **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.	*BT*, **2000**, 4 (Ukrainian edition)	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug

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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.	*Omeopatia Oggi*, **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 retinopathy.	*Boll. Oculist.*, **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 Heliantus tuberosus D1 in the complementary treatment of overweight patients.	*Therapiewoche*, **1994**, 44: 34-39.	The homeopathic medicine proved therapeutically superior
Complications of haemodialysis	Hariveau E.	Clinical research at the Boiron Institute.	*Homéopathie*, **1987**/5; 55-8.	The homeopathic medicine proved therapeutically superior
Complications of haemodialysis	Saruggia M., Corghi E.	Effects of homeopathic dilutions of China rubra on intradialytic symptomatology in patients treated with	*Br. Hom. J.*, **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.	*Homéopathie Française*, **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.	*In: Recherches Homéopathiques (Boiron J., Belon P., Hariveau E., eds.). Fondation Française pour la Recherche en Homéopathie*, **1986**. Lyon: 71-74.	The homeopathic medicine proved therapeutically superior
Kinetosis (motion sickness)	Dexpert M.	Prevention of motion sickness with Cocculine.	*Homéopathie Franc.*, **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.	*Proc. 42nd Congr. LMHI*, **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.	*Berl. J. Res. Hom.*, **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.	*J. Head Trauma Rehabil.*, **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.	*Br. Homeopath. J.*, **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.	*BM,* **2001**, 4. **Pubblicato 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	Hourst P.	Acknowledgement of the efficacy of homeopathy.	*Université P. et M. Curie (Thesis).* 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.	*Cah. Biothér.*, **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.	*Cahiers d'Otorhinolaryngologie*, **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 Oscillococcinum/ placebo.	*Proposta Omeopatica 3*, Anno IV, ottobre **1988**.	The homeopathic medicine proved therapeutically superior
Coryza	Mossinger P.	Study of treatment of rhinorrhoea with Euphorbium D3.	*Allg. Hom. Zeitung*, **1982**, 227: 89-95.	The homeopathic medicine proved therapeutically superior
Otitis media	Mossinger P.	The treatment of otitis media with Pulsatilla.	*Kinderarzt*, **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.	*Pediatr. Infect. Dis. J.*, **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.	*Complemen. Ther. Med.*, **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.	*Arzneim. Forsch./Drug Res.*, **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.	*Biol. Ther.*, **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.	*Br. J. Clin. Pharmac.*, **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.	*Medicina Naturale*, **1994**/6.	The homeopathic medicine proved therapeutically superior
Influenza syndrome	Heilmann A.	A combination injection preparation as a prophylactic for flu and common colds.	*Biol. Ther.*, **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.	*Medicina Naturale*, **1995**/6.	The homeopathic medicine proved therapeutically superior
Bronchial asthma	Matusiewicz R.	The efficacy of Engystol in cases of bronchial asthma treated with corticosteroids.	*La Medicina Biologica*, **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.	*La Medicina Biologica*, **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., Haidvogl M., Heger M.	Homeopathy and Conventional Medicine: an outcome study comparing effectiveness in a primary care setting.	*The Journal of Alternative and Complementary Medicine*, **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.	*Arzheim Forsch./Drug Res.*, **1981**, 31: 732-736.	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug
Common cold	Maiwald L., Weinfurtner 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-	*Arzheim Forsch./Drug Res.*, **1988**/4.	The homeopathic medicine was not therapeutically inferior to the allopathic reference drug
Otitis media	Kruse K.	Subject reported in the volume.	*Edition Forsch. Hippokrates Verlag, Stuttgart,*	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.	*Br. Homeopath. J.*, **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.	*BM,* **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).	*Université de Grenoble (Thesis),* **1981**.	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.	*Press Med.*, **1984**, 13: 833.	The homeopathic medicine proved therapeutically superior
Dynamic ileus	Aulagnier G.	The action of post-operative homeopathic treatment.	*Homéopathie,* **1985**, 6: 42-45.	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).	*Université de Grenoble (Thesis),* **1981**.	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.	*Pédiatrie,* **1990**, 45: 465-466.	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.	*Université de Nantes (Thesis),* **1981**.	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.	*Medicina Biologica (in Spanish)* **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.	*La Medicina Biologica*, **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.	*Cancer* – 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.

PUBLISHED IN: **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: **1988** imittel Forschung/Drug Research, **1988**

■ 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:

at least **3** of the following:
– abnormal fatigue
– loss of appetite
– excessive thirst
– insomnia
– chills
– excessive perspiration
– runny nose
– cough

at least **2** of the following:
– sore throat
– earache
– aches in limbs
– headache

at least **1** of the following:
– nasal secretion
– swelling of lymph glands
– eardrum retraction
– sounds indicating bronchitis.

■ 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 Aconitum Heel®*	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 Aconitum Heel®*	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.

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.
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)

once a week

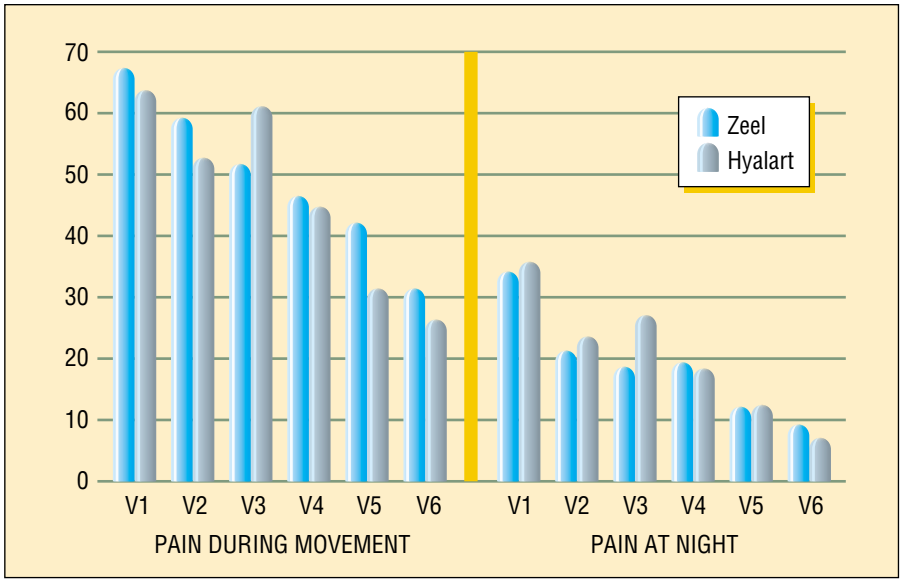
■ INCLUSION CRITERIA:	1) primary osteoarthritis of the knee clinically diagnosed on the basis of statement of pain symptoms in the knee 2) radiological finding of osteoarthritis of the knee 3) constant pain for at least 3 months, with no signs of acute active inflammation 4) written informed consent.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

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."

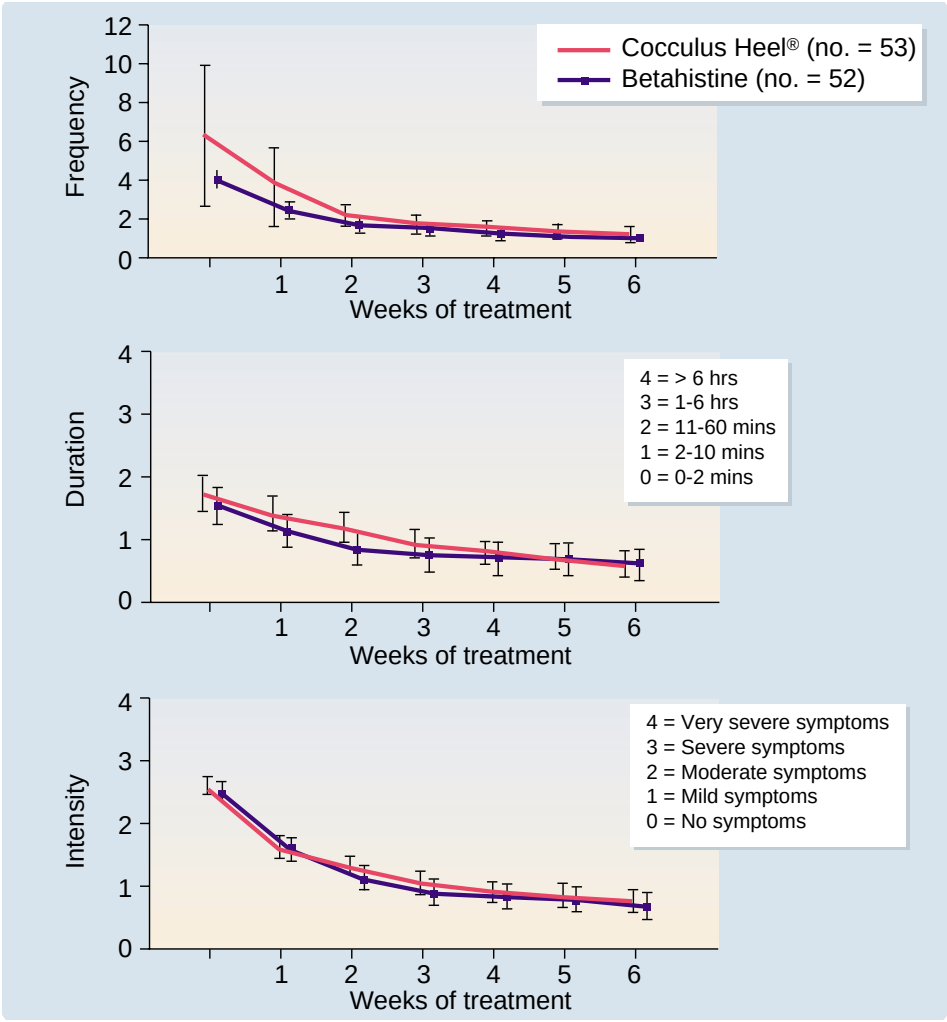
■ FINAL RESULT:

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® (ribosomial 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)

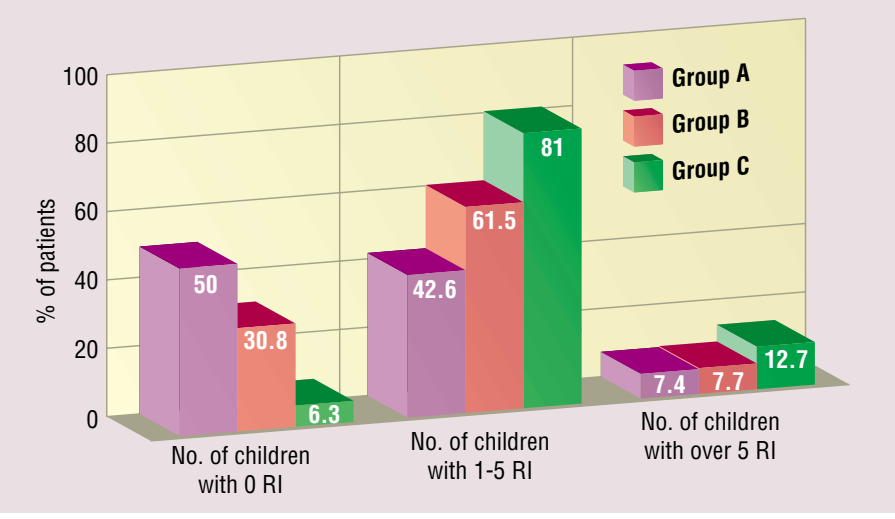
■ DOSE:	**1) homeopathic protocol:** – Engystol® N tablets (1 tablet every morning for 20 consecutive days a month for 3 consecutive months) – Lymphomyosot® drops (10 drops b.i.d. for 3 consecutive months) – Echinacea comp. S ampoules (2 ampoules per os a week for 3 consecutive months). **2) allopathic protocol:** – 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)
■ EVALUATION CRITERIA:	– number of episodes of respiratory infections – total number of days of fever – use of antibiotic
■ THERAPEUTIC EFFICACY:	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
■ AUTHOR'S CONCLUSIONS:	*"The absence of side effects and good compliance with the protocol make homotoxicological treatment suitable for large-scale use".*
■ FINAL RESULT:	the homeopathic product proved superior to the corresponding allopathic reference protocol.

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

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

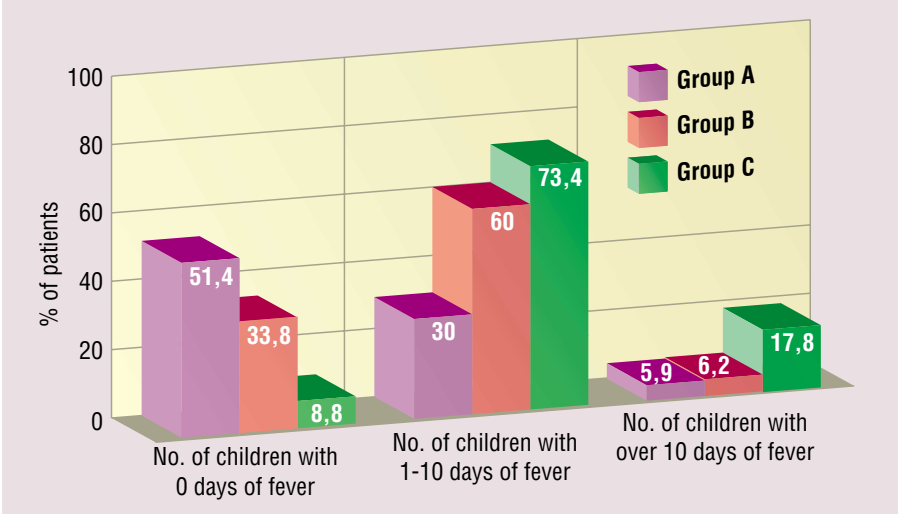


Graphic representation of the above table.

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

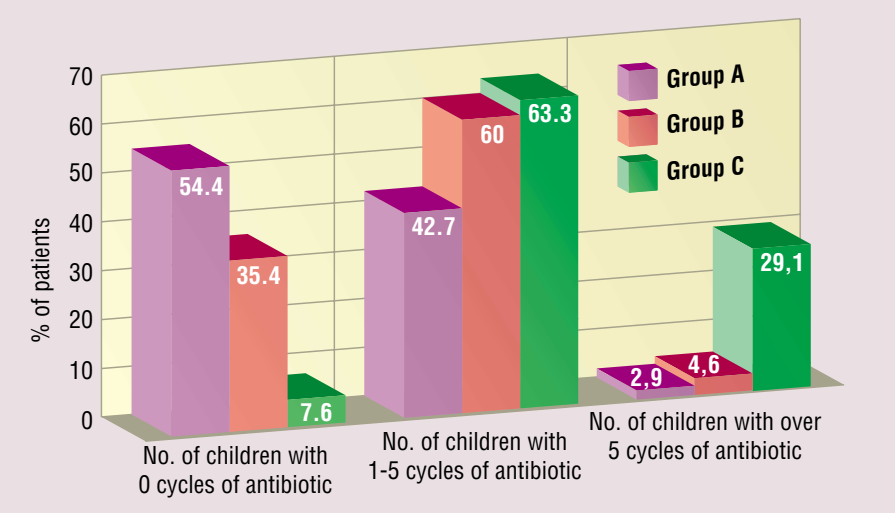


Graphic representation of the above table.

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:

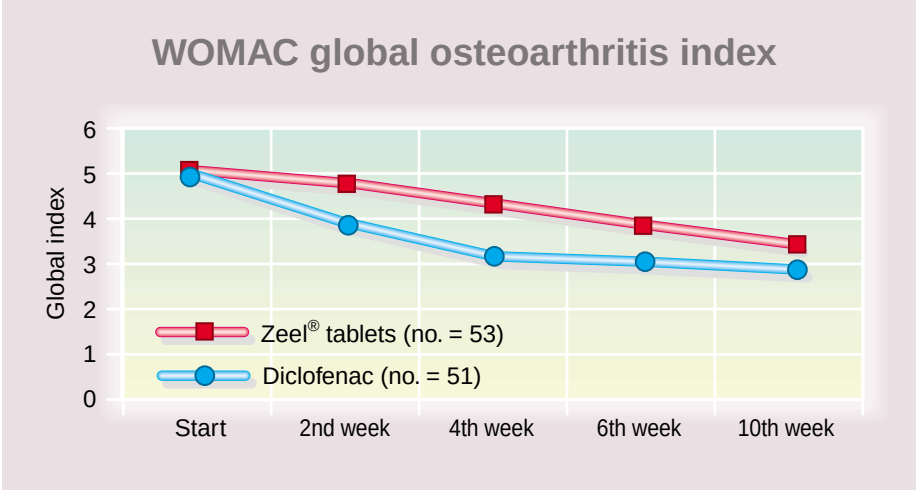
"This controlled clinical trial demonstrates that the efficacy of Zeel® comp., in the treatment of mild to moderate osteoarthritis of the knee is equivalent to that of diclofenac. The trial also confirms the therapeutic safety of Zeel® tablets".

■ 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, laparocele, 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:

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)

Allopathic group 1 Ceftazidime =
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 =
2 g i.v. 2 hours before and at the end of the operation, and every 24 hours in the next 48 hours

■ EVALUATION CRITERIA:

1) variation in skin temperature
2) variations in leucocyte concentrations
3) wound healing (1st intention, 2nd intention)
4) onset of infection
5) duration of treatment
6) duration of hospitalisation
7) basic disorder
8) associated therapeutic procedures

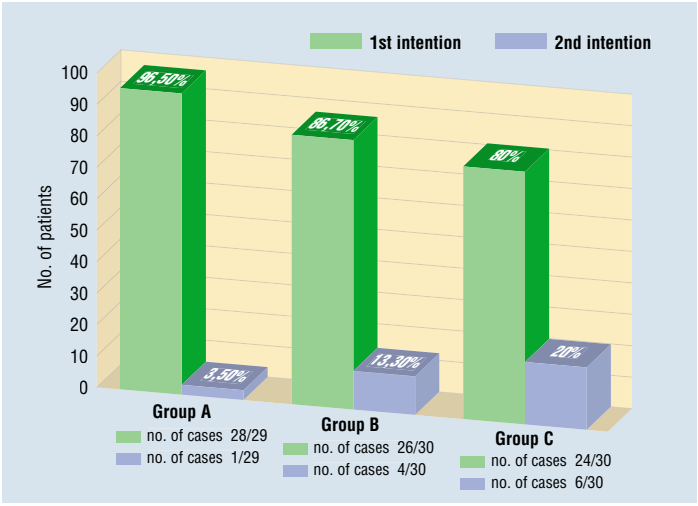
■ AUTHOR'S CONCLUSIONS:

"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."

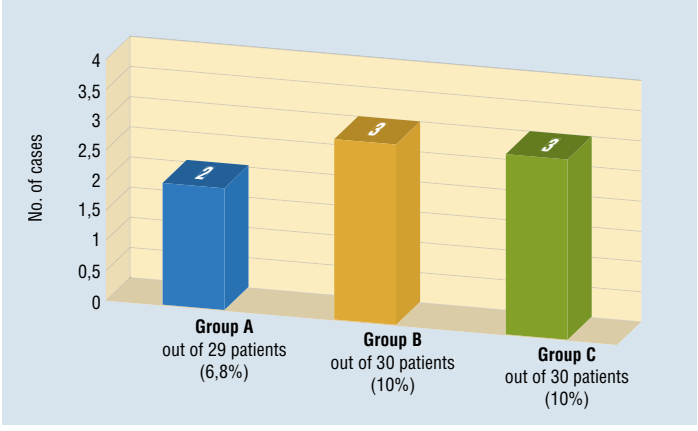
■ FINAL RESULT:

the homeopathic protocol was not inferior to the two allopathic protocols in preventing post-operative infections.

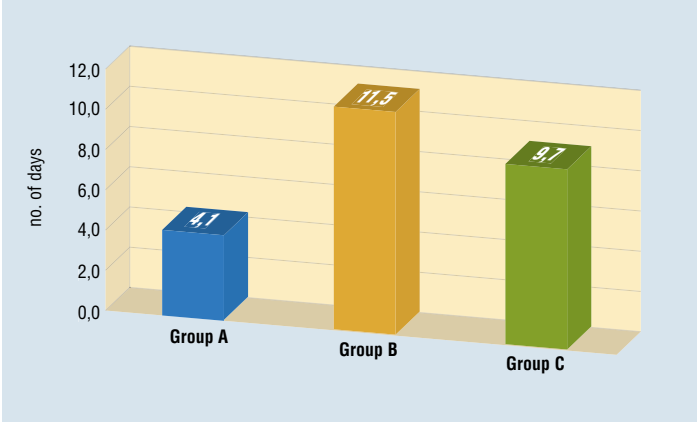
TOTAL COST:	**homeopathic treatment**	**€ 20.70**
	allopathic treatment 1	**€ 126.42**
	allopathic treatment 2	**€ 159.68**



Wound healing process.
Group A = Homeopathic group
Group B = Allopathic group 1
Group C = Allopathic group 2.



Post-operative infections.
Group A = Homeopathic group;
Group B = Allopathic group 1
Group C = Allopathic group 2.



Mean hospitalisation period.
Group A = Homeopathic group
Group B = Allopathic group 1
Group C = Allopathic group 2.

8

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: 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

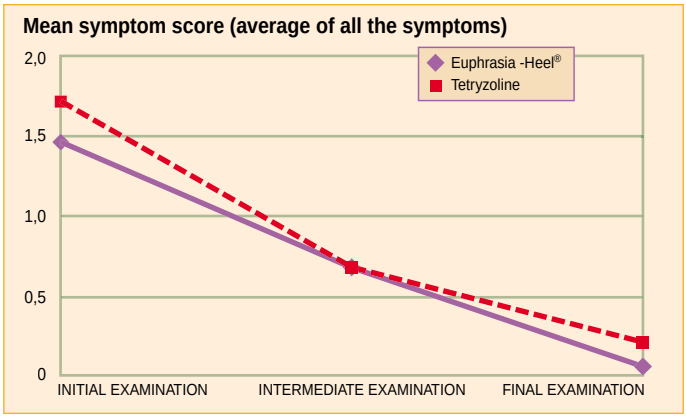
TREATMENT:
- **Homeopathic group =** Euphrasia-Heel® single-dose eyedrops = 456 patients
- **Allopathic group =** Tetryzoline 0.5 mg single-dose eyedrops = 313 patients

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

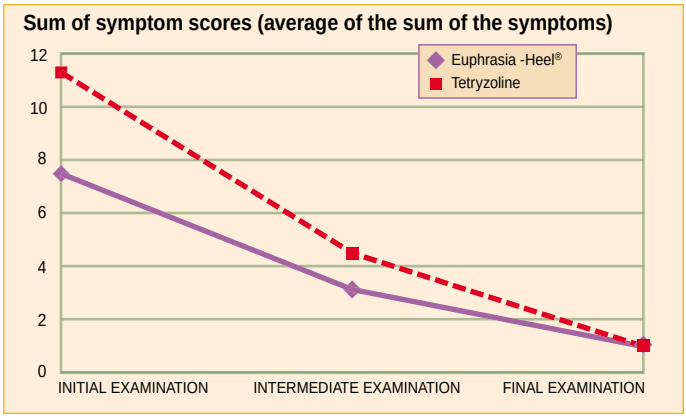
DURATION OF THE TRIAL: 2 weeks

■ 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.

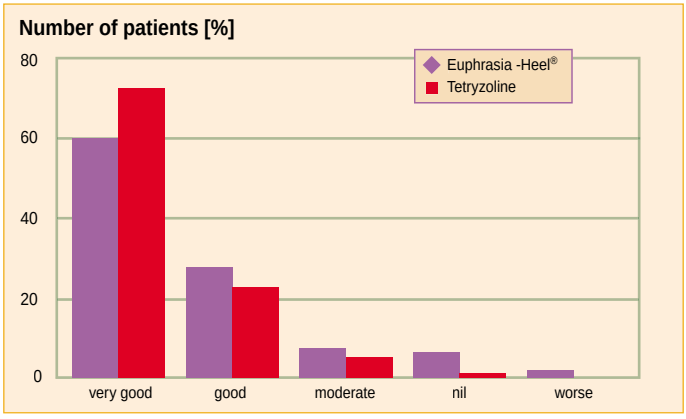
TOTAL COST:	**homeopathic treatment**	**€ 8.00**
	allopathic treatment	**€ 8.52**



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:

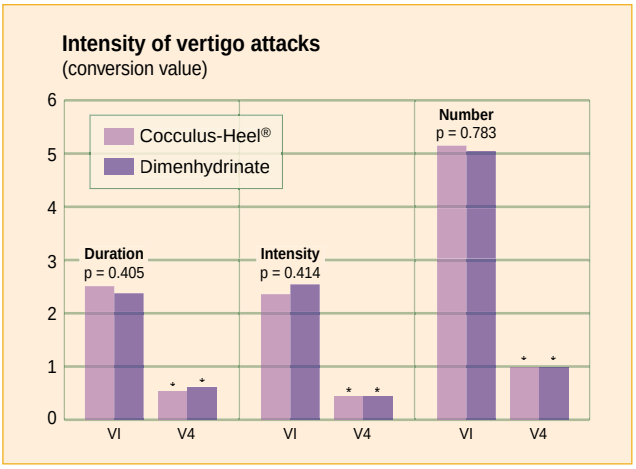
"… in conclusion, this multicentric controlled trial confirms that Cocculus-Heel® is a safe, effective homeopathic treatment option for vertigo of differing aetiologies, and is not inferior in therapeutic terms to allopathic drugs containing dimenhydrinate."

■ FINAL RESULT:

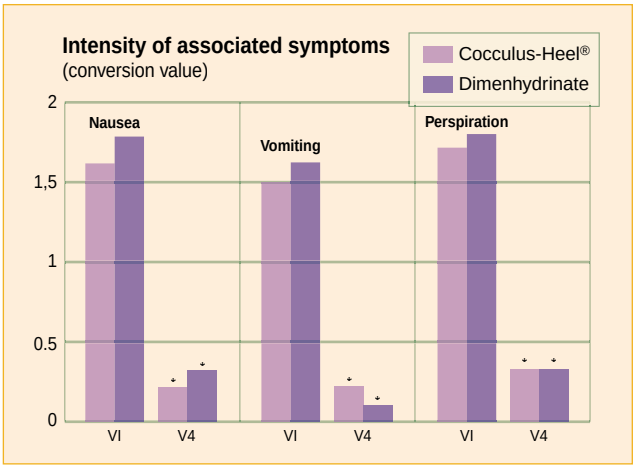
Cocculus-Heel® is not inferior to dimenhydrinate in the treatment of forms of vertigo with various aetiologies.

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.