*Correspondence: Alastair Gray, Endeavour College of Natural Health, Australia.
E-mail: alastaircgray@gmail.com (A. Gray)

Background: Debate has emerged over the need to put proving's through formal ethics processes. No one argues that we should have ethical provings. But the process is at question, as in some countries there are significant hurdles to robust homeopathic research, unsympathetic ethics boards, and poor understanding of provings in general. Further, many have argued that by doing this kind of research, homeopathy is losing control of its ability to direct the narrative.

Concerns have been raised about the clinical relevance of many modern provings, health of provers, safety, adverse reaction processes, exit processes, prover coercion etc. In some countries (US, South Africa, Australia) thorough ethics processes have been put in place, sometimes constraining but more often, creating better and more transparent proving processes. Concurrently, proving guidelines are being discussed and re-written at the professional level.

Method: Endeavour College has previously put homeopathic provings to an ethics board. While successful each time there were significant discussion points, conflict, compromise and adaptation to the process depending on the substance involved and the make up of the panel.

Results: Endeavour College now has 5 completed proving's that have moved through this ethics process. In some years the successful submission has only been possible by;

- Re-proving existing substances
- Clearly naming the remedy beforehand
- Guaranteeing students could not be coerced or participate at all
- Altering conventional proving method

This paper goes into the specifics of the response when challenged by the ethics board.

Discussion/conclusion: For the successful navigation of a proving through a formal ethics process, flexibility, listening, adaptation, agility and persistence are required to bring a trial home. Even with this rigorous ethics process a successful clinically relevant proving cannot be guaranteed. Excellent method and supervision is also necessary, but a transparent ethics approval process is a fundamental and important step in the process.

Homeopathic treatment of respiratory illnesses in children: results from two randomized trials

James A Taylor and Jennifer Jacobs*

Department of Epidemiology, University of Washington School of Public Health and Community Medicine, USA

*Correspondence: Dr Jennifer Jacobs, Department of Epidemiology, University of Washington School of Public Health and Community Medicine, United States of America.
E-mail: jjacobs@igc.org (J. Jacobs)

These studies were done to determine if homeopathic preparations are useful in the treatment of URI's in children, especially when there are no conventional treatments available and/or antibiotics are to be avoided. In the first study, children 6 months − 11 years old, diagnosed with AOM and managed with a delayed antibiotic approach, were randomized to standard therapy alone or standard therapy plus a homeopathic ear drop preparation. The primary outcome was whether or not an antibiotic prescription given at the index visit was filled; any antibiotic use was a secondary outcome. During the 12−15 day follow-up period, significantly fewer parents of children randomized to the homeopathic ear drops group filled the antibiotic prescription compared to those of children receiving standard therapy alone (26.9% and 41.2%, respectively, P = .032). In the second study, children ages 2−5 years old diagnosed with upper respiratory infection were randomized to receive a homeopathic combination product for cold and cough or a placebo. Parents were instructed to give a dose of study medication as needed for relief of URI symptoms up to 6 times per day for three days. Parents recorded changes in symptoms 1 hour after each dose, as well as changes in overall severity of URI symptoms in twice daily diaries. There was no difference in symptoms one hour after the dose between those receiving the homeopathic preparation compared to placebo. However, the homeopathic group reported a statistically significant improvement in 3 of the 4 URI symptoms at 12 and 24 hours after enrolment as well in a composite cold score. These studies should encourage health care providers to utilize homeopathy as an alternative to conventional therapies in the treatment of URI's in children.

Keywords: URI, Acute otitis media, Homeopathic combination products

Homeopathic Pathogenetic Trials (provings) do not always match homeopathic clinical practice. Possible answers from the qualitative research tradition

Jean Pierre Jansen*

Physician for Homeopathy and Neural Therapy, The Netherlands

*Correspondence: Jean Pierre Jansen.
E-mail: jpjansen@antenna.nl (J.P. Jansen)

Traditionally, Homeopathic Pathogenetic Trials (HPT, proving) are published following the head to toe schema. This is a relatively easy format for the unprejudiced observer. It leads to the first cured cases if one applies

the analytical methods of a few 19th century authors. Thus the materia medica of that remedy is enriched and extended. This cyclic process that ideally arrives at a saturated, generally accepted remedy picture is called clinical verification.

However, since the early 1990's new analytical procedures developed in clinical work (e.g. Sankaran: basic delusion, vital sensation; Sherr: dynamic verb; Scholten: groups; Yakir, Scholten: plant taxonomy; Vervarcke: vital approach; Whitmont, Lilley, Cicchetti: archetypes; etc.) have been (re-)introduced. The C4-approach seems the only system embedded in a particular proving design. These developments pose the question, if the traditional proving method still matches modern clinical work.

The new analytical methods can be applied at various stages of the materia medica knowledge formation process: a) during data collection in provings, where instructions for provers and supervisors may reflect one or another new approach, b) during analysis of the proving symptoms after data collection, defining the remedy-image for the first clinical verification cycle, and c) at various moments during the clinical verification phase. It is unclear, whether the observer can and should keep an unprejudiced position (Hahnemann, 1835) in all instances.

Qualitative research is a research tradition (mainly in ethnology, sociology, psychology, nursing) that has developed multiple procedures dealing with this problem and can enhance and may support the quality and credibility (validity) of qualitative research, such as provings. This presentation gives an overview of questions, viewpoints and methods that provide directions to improve proving methodology.

Keywords: Proving methodology; Homeopathic Pathogenetic Trials; Clinical verification; Qualitative research.

A randomized open comparative clinical trial on the effectiveness, safety and tolerability of a homeopathic medicinal product for frequent acute upper respiratory tract infections in children

M Jong[1,2,*], M van Vliet[1,2], J Burkart[1,2], P Klement[1,2] and E Baars[1,2]

[1]*Louis Bolk Institute, The Netherlands*
[2]*Louis Bolk Institute, Sweden*

[*]Correspondence: Dr Miek Jong, Louis Bolk Institute, Netherlands and Sweden.
E-mail: m.jong@louisbolk.nl (M. Jong)

Background: Homeopathy may be an effective alternative for antibiotics in the treatment of recurrent upper respiratory tract infections (URTI) in children. More research is warranted to further explore this potential.

Objective: To investigate the effectiveness, safety and tolerability of the homeopathic product Immunokind, in children for the prevention of recurrent URTI in comparison to another homeopathic product.

Design: A prospective, multicenter, randomized, open, comparative clinical study with two parallel treatment groups at four outpatient pediatric clinics in Russia.

Methods: Children aged ≤ six years with susceptibility to URTI (≥ three occasions during the last six months) were enrolled from February 2010−September 2011 in the study. They were randomized to receive for three weeks either Immunokind tablets (intervention group) or Aflubin tablets (control group), with a six months post-treatment follow-up period. Exclusion criteria were acute URTI, the exacerbation of chronic URTI and severe comorbidity. Primary effectiveness endpoint was change in the frequency of URTI after three and six months of follow-up compared to baseline frequency of URTI (last 12 months prior to study). Secondary endpoints were changes in total complaints, symptoms scores, antibiotic use, treatment satisfaction, tolerability and safety.

Results: A total of 201 children (100 in intervention group, 101 in control group) were randomized. Mean age of children was 34.2 ± 20.0 months (intervention group) and 35.8 ± 19.9 months (control group). Preliminary analysis demonstrated that the number of URTI decreased after six months post-treatment compared to baseline (last 12 months prior to study start), both in the intervention (6.5 ± 2.3 to 2.1 ± 1.6) and control group (6.4 ± 2.2 at baseline to 2.5 ± 1.4). Analysis with respect to concomitant antibiotic use and other outcome parameters is ongoing and will be presented at the conference.

Conclusions: Immunokind tablets appeared to be effective in preventing recurrent URTI.

Keywords: Respiratory tract infections, Children, Homeopathy, Safety, Antibiotic use

Results of an international, randomised, controlled clinical trial with a complex homeopathic medication in feverish upper respiratory tract infections

M Thinesse-Mallwitz[1], V Maydannik[2], T Keller[3], S De Jaegere[1] and P Klement[1,4,*]

[1]*GP Surgery, Munich, Germany*
[2]*Bogomolets National Medical University, Kiev, Ukraine*
[3]*ACOMED Statistik, Leipzig, Germany*
[4]*Deutsche Homöopathie-Union, Karlsruhe, Germany*