

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

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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 \leq six years with susceptibility to URTI (\geq 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

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