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 ≤ 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

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Background: Complex homeopathic medications are an opportunity to introduce homeopathy in countries without homeopathic tradition and in cases where daily routine doesn't allow homeopathic repertorisation for an individual therapy. We set out a clinical trial to investigate the effectiveness and safety of the complex homeopathic medication Influcid® as add-on therapy to usual care in patients suffering from upper respiratory tract infections (URTI), the most frequently occurring illness in the world with great impact on health economics in terms of missing days at work.

Methods: Between Nov 2010 and Apr 2011 we conducted a randomised, controlled clinical trial in Germany and Ukraine. Patients aged 1−65 years with URTI were included. To all patients standard symptomatic medication (Paracetamol, Ambroxol and/or Oxymetazoline) was offered on demand depending on their symptoms. The test group received additionally Influcid (active ingredients: Aconitum D3, Bryonia D2, Eupatorium perfoliatum D1, Gelsemium D3, Ipecacuanha D3, Phosphorus D5) for seven days.

The Wisconsin Upper Respiratory Symptom Survey (WURSS-21) was used to assess URTI symptoms. Primary outcome measure was the response at day 4, defined as the absence of fever and the absence or very mild degree of URTI-symptoms.

Results: 523 patients (265 test and 258 control group) were randomised in 22 centres. Response at day 4 differed highly significantly in favour of the Influcid-group (15.4% vs. 6.7%, Δ 8.7%; 95%-CI: 2.9−14.5%; p = 0.0018; Chi^2-Test). Dosage and duration of symptomatic treatment was significantly lower and symptoms alleviated 1−2 days earlier in the Influcid group.

Eleven adverse events were classified as probably or possibly treatment related: one adverse event was possibly related to Influcid (vomiting) and ten to the symptomatic therapy.

Conclusion: The study data suggest Influcid as a therapeutic option in the treatment of URTI as it effectively reduced URTI symptoms and the need for conventional symptomatic treatment and was well tolerated.

Keywords: Upper respiratory tract infections, Fever, Randomized controlled clinical trial, Homeopathy, Complex homeopathic medication

Effect of ultra-high dilutions of *Lycopodium clavatum* on reproductive and sexual functions in aged male Wistar albino rats

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Introduction: Ultra-high dilutions of *Lycopodium clavatum* (LC) is commonly used in the homoeopathic treatment of various disorders in male reproductive system. This efficacy of LC in alleviating male reproductive system disorders is exploited in this study on a reproducible, natural, animal experimentation model of ageing to ascertain the pharmacodynamics of homeopathic ultra- high diluted medicines.

Methods: Aged male Wistar albino rats were grouped randomly into six groups (n = 6), where the 2nd, 3rd, 4th and 5th group animals were treated with LC Q, 6C, 30C and 1M respectively. 1st group served as aged control and 6th group served as vehicle control. LC was given at a dose of 20 μl/animal/day per-orally for 60 days. Estimation of serum testosterone was done at the beginning and end of the experiment. After 60th day, of testis and epididymis were analyzed. Following sperm parameters were studied *viz.*, Viability, Concentration, Motility, Morphology, Morphometry, Acrosomal intactness, Membrane permeability (HOST) and Nuclear condensation (AO-Assay). Testicular Enzymic, Non-Enzymic antioxidants and Lipid peroxidation were analyzed .Test for potency and mating behavior assessment was done every 30 days till the end of the study. Results were statistical analyzed.

Results and discussion: Testosterone levels were increased in drug treated animals. Sperm parameters of drug treated groups were significantly better compared to the aged control and vehicle control groups. Histopathology examination revealed a better spermatogenic status in the treatment groups than the control groups. Mating behavior assessment and test for potency showed better sexual performance in drug treated groups than control groups. Among the drug treated groups, 30C and 1M treated groups showed significant better results compared to Q and 6C treated groups.

Conclusion: Efficacy of LC in sexual sphere was confirmed using a stable animal model i.e. aging. Effectiveness of LC was further appreciated in ultra-high dilutions compared to its lower dilutions.

Keywords: Homeopathy, Lycopodium clavatum, Aging, Andrology, Sperm, Rats

Exploring the model of murine infection by *Trypanosoma cruzi* to investigate treatment with highly diluted drugs: the influence of *Lycopodium clavatum* or *Phosphorus* in Wistar rats