

*Correspondence: Petra Klement, MSc, Deutsche Homöopathie-Union DHU-Arzneimittel GmbH & Co.KG, Germany.
E-mail: Petra.klement@dhu.de (P. Klement)

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%; $p = 0.0018$; χ^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

Ganesh Lakshmanan* and Seppan Prakash

University of Madras, India

*Correspondence: Dr Ganesh Lakshmanan, B.H.M.S., M.Sc., (Ph.D), Dept. of Anatomy, University of Madras, Chennai, India.
E-mail: drganeshbhms@yahoo.com (G. Lakshmanan)

Introduction: Ultra-high dilutions of *Lycopodium clavatum* (LC) is commonly used in the homeopathic 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 μ l/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

Silvana Marques de Araújo*,
Camila Fernanda Brustolin, Paula Fernanda Massini,
Neide Martins Moreira,
Carlos Edmundo Rodrigues Fontes
and Denise Lessa Aleixo

Universidade Estadual de Maringá, Brazil

*Correspondence: Prof Silvana Marques de Araújo,
Universidade Estadual de Maringá, Brazil.
E-mail: smaraujo@uem.br (S.M. de Araújo)

Research using highly diluted drugs has advanced significantly with increasing number of consolidated research groups. This work evaluates the influence of highly diluted *Lycopodium clavatum* or *Phosphorus* in Wistar rats infected by *T. cruzi*. The experiment was conducted as a blind, controlled and randomized by draw assay and was approved by university ethical committee. 75 male rats (*Rattus norvegicus*, Wistar lineage), 45 days old, intraperitoneally inoculated with 5×10^6 *T. cruzi* Y-strain blood trypomastigotes were divided into three groups: IC (infected control group, treated with 7% hydroalcoholic solution), Ly (infected treated with *Lycopodium clavatum* 13CH), Phos (infected treated with *Phosphorus* 13 CH). All treatments were offered ad libitum on the second day before the infection, and on the second, fifth and seventh day after infection, provided for 16 consecutive hours. Evaluated parameters: weight, temperature, water and food intake, amount of excreta, intestinal length and diameter, hair aspect, stool consistency, heart and respiratory rates, pre-patent period, parasitemia peak, total parasitemia, evaluation of myenteric neurons, inflammatory infiltrate and cytokines production. Data were statistical compared. *Lycopodium* and *Phosphorus* have significant beneficial effects on the clinical evolution of the treated animals. No significant difference was observed for any parasitological parameter evaluated. Ly and Phos groups showed protection of distal colon neurons numbers. In the heart, liver and intestine animals treated with *Lycopodium* and *Phosphorus* showed significant less inflammation compared to IC. In striated skeletal muscle, *Phosphorus* animals showed the number of inflammatory foci higher than IC. In a sequential evaluation, IL1- α , IL1- β , IL4, IL6, IL10, IL12, TNF- α , IFN- γ and GM-CSF levels varied significantly different for *Lycopodium clavatum* and *Phosphorus*. The homeopathic treatment with *Lycopodium clavatum* or *Phosphorus* medicines (13CH) promoted, in a different way, beneficial effects on several parameters evaluated in *T. cruzi* infection of Wistar rats. The treated groups establish balance of host-parasite relation differently, with lower cell and tissue damage to the infected host. *Lycopodium clavatum* and *Phosphorus* modifies the animals' immune response, promoting less inflammation and protecting the intestine, preserving the myenteric neuronal population.

Keywords: Trypanosoma cruzi, Clinical evaluation, Myenteric neurons, Cytokines, Homeopathic medicine, *Lycopodium clavatum*, *Phosphorus*

Systematic review and meta-analysis of randomised, placebo-controlled, trials of individualised homeopathic treatment

Robert T Mathie*, Michel Van Wassenhoven,
Jennifer Jacobs, Menachem Oberbaum, Joyce Frye,
Raj K Manchanda, Helmut Roniger, Flávio Dantas,
Lynn A Legg, Jürgen Clausen, Sian Moss,
Jonathan RT Davidson, Suzanne M Lloyd, Ian Ford
and Peter Fisher

British Homeopathic Association (BHA), UK

*Correspondence: Dr Robert T Mathie, British Homeopathic Association (BHA), UK.
E-mail: rmathie@britishhomeopathic.org (R.T. Mathie)

Background: The BHA's programme of systematic reviews of randomised controlled trials (RCTs) of homeopathy distinguishes key attributes of study design and intervention: placebo controlled *cf.* other-than-placebo controlled; individualised *cf.* non-individualised homeopathy; treatment *cf.* prophylaxis.

Objective: This presentation centres on the hypothesis: For the broad spectrum of medical conditions that have been researched using RCTs, the main outcome of an individualised homeopathic treatment approach using homeopathic medicines is distinguishable from that of the same approach using placebos (i.e. individually prescribed homeopathic medicines have specific effects). The impact of internal validity (risk of bias, RoB) and model validity (MV) informed the detailed interpretation of results.

Methods: 31 papers (reporting a total of 32 RCTs) were eligible for systematic review. For each trial, the separate ratings for RoB and MV were merged to obtain a single overall designation ('high', 'moderate', 'low' or 'very low' quality). The identified main outcome measure was extracted, if possible, for each trial and used in meta-analysis.

Results: Combining assessment of MV and RoB identified 3 trials of 'high quality', 8 of 'moderate quality', 18 of 'low quality' and 3 of 'very low quality'. This hierarchy was little different from that attributed to RoB alone, and so the meta-analysis findings were essentially unchanged by accommodating MV: a small, statistically significant, pooled odds ratio (OR) favouring homeopathy (mean = 1.53; N = 22) that is robust to sensitivity analysis based on best evidence (mean OR = 1.98; N = 3). There was no association between a trial's MV and RoB or direction of treatment effect.

Discussion: Accommodating MV in the quality appraisal of RCTs does not alter the conclusion that individually prescribed homeopathic medicines may have small, specific, treatment effects. This conclusion reflects evidence in individualised homeopathy across a broad spectrum of medical conditions and thus transcends condition-specific analysis.