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ORIGINAL PAPER

Hepatitis C Nosode: The preparation and homeopathic pathogenetic trial

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Background: **A double blind, randomized placebo controlled homeopathic pathogenetic trial (proving) of Hepatitis C (Hep C) nosode was conducted with the aim to introduce the new nosode in homeopathic pharmacopeia.**
Method: **Documentation included approval by Ethics Committee, Informed Consent Form, Laboratory investigations, safety and ethical measures. The volunteers were trained to write data in prescribed diaries and data were analyzed. A fifteen-step method was used in the preparation of Hep C nosode (genotype I and III), allowing future preparation of an identical nosode. 22 volunteers were entered, 15 received Hep C nosode in 30c potency, 7 received placebo, once a week for four weeks.**
Results: **The Hep C nosode was associated with qualitatively and quantitatively distinct symptoms, which can be applied in clinical practice. A significantly higher incidence of pathogenetic effect of homeopathic medicine compared to placebo was observed. Safety was documented. The nosode produced symptoms comparable with Hep C disease.**
Conclusion: **An improved method of nosode preparation was used. A double blind, randomized placebo controlled pathogenetic trial of the Hep C nosode generated guiding symptoms, which may facilitate its prescription in practice. The nosode should be further explored for the treatment of immunologically mediated diseases, infections including Hep C, fibrotic pathology and chronic inflammatory disorders.** *Homeopathy* (2013) **102**, 207–214.

Keywords: Hepatitis C; Nosode; Drug proving; Homeopathic pathogenetic trial; Potentization; Standardization; Double blind; Randomization; Placebo control; Safety; Symptoms

Introduction

The Hepatitis C virus, previously known as non-A, non-B virus, was postulated in 1970 and demonstrated in 1989.[1] Hepatitis C is a serious and chronic infection. An estimated 130–170 million people worldwide and about 1.4% Americans are infected with hepatitis C.[2,3] The epidemiology of hepatitis C in India has not been studied systematically.[4] Hepatitis C causes hepatitis, cirrhosis, malignancy, fibrotic changes, thrombocytopenia, hepatic portal hypertension, chronic organ inflammation, etc. Hepatitis C is the cause of 27% of cirrhosis cases and 25% of hepatocellular carcinoma worldwide.[5]

The method of nosode preparation used for the product test in this trial was designed and approved with the help of a team comprising virologist, immunologist, biotechnologist, legal attorney, homeopaths, pharmacologist, microbiologist, social worker, and hepatologist.

In this project, placebo effects were filtered out by:

1. Placebo controlled, blinded, randomized design.
2. Elimination of study of symptoms if they also occurred in run-in period, in the same volunteer.
3. Comparison of proving symptoms with known symptoms of the disease.
4. Quantification of duration and intensity of symptoms and days of appearance, quantified.

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5. Number of volunteers who produced particular symptoms.

The study has substantiated previous work.[6,7] The project of Homeopathic pathogenetic trial (drug proving) was designed to evaluate the clinical symptoms of Heptatis C (Hep C) nosode in healthy volunteers. Volunteers were blind to the identity of the substance as well as to whether they received verum or placebo.

Objective

To prepare a polyvalent Hep C nosode using a well-defined, standardized method. To conduct a double blind placebo controlled pathogenetic trial with the Hep C nosode, on healthy humans with the aim of deriving indications for clinical application.

Materials and methods

Preparation of nosode

The Hep C nosode was prepared using an elaborate 15-step method (patent pending with the author); as the method underwent some technical modernization. In brief, Institutional Ethics Committee approved the project of Hep C nosode preparation. Informed consent forms were served to the patient-volunteers who donated their blood. Two patients were separately screened with Hep C geno-type I and III respectively, were ruled out for possible co-infections such as HIV, Hep B, Gonorrhea, Syphilis, etc.; blood was drawn, serum expression was done, serum filtration was carried out to remove large particles and other possible bacteria.

This resulted in serum containing specific number of Hep C virus particles, without other possible co-infections as well as large protein particles. The serum was standardized in terms of viral load using the RT-PCR method. Hep C genotype I virus copies were 2,94,000 IU/ml and Hep C geno-type III virus copies were 10,30,000 IU/ml. Some amount of sera was lyophilized for future use. 0.03 ml each of Hep C geno-type I and III were mixed with 2.94 ml of water for injection (as vehicle) for potentization.

To further standardize the potentization process, force parameters of the mechanical potentizer were documented. Potencies up to 15c were prepared using water for injection and subsequently (up to 30c and more) with alcohol as vehicle, with 0.03 ml−2.97 ml (1:99) ratio. Micropipettes were used instead of following *drop* method. Safety check (for human use) was carried out for Hep C nosode 30c potency by RT-PCR method. Samples of HCV nosode 30c potency were tested for presence of HCV virus by Hepatitis C virus (HCV) RNA quantification (viral load), COBAS TaqMan method, which was done with multiple samples, by spiking with positive and negative controls. The serum of mother preparation (containing Hep C virus) was used as positive control. It was established and documented that all the samples of HCV nosode 30c were negative for HCV virus. All the blood work was done at accredited Metropolis Laboratory and Reliance Life Sciences Laboratory.

Volunteers and method

The author was the principal investigator; a double blind, randomized placebo controlled study was conducted at Life Force research center. A blinded person who was not involved in the study procedure generated randomization number table. The drug was proved in 30c potency on 22 volunteers with randomization ratio of 2:1, 15 volunteers received and verum, seven volunteers matching placebo. The study involved seven females and 15 males out of 22 volunteers; six females received active and one placebo; nine males received active and six placebo.

The dose and repetition was 30c potency, one dose, once a week for 4 weeks. Volunteers and investigator were blinded to the identity of the substance and verum/placebo allocation. The volunteers signed Informed Consent Forms. Blinding was maintained until the completion of the proving period. The proving volunteers were selected based on the inclusion and exclusion criteria. The volunteers, aged 18−45 years, from different walks of life, including homeopathic students and homeopaths participated. The volunteers underwent the pre-observation and post observation investigations namely X-ray chest, electrocardiogram, routine laboratory investigations and pregnancy tests, as applicable.

Each volunteer completed intake of the five doses, one dose of placebo on the first day with seven days of run-in period; then one weekly dose of medicine for next 4 weeks. The symptoms generated during the trial period were noted (up to 6 weeks) by the volunteers in the diary provided to them and were cross-examined and elaborated by the proving master. Proving master (investigator) had compiled the data after decoding (opening the blind).

Guidelines, ethics, compliance and approvals

We based the pathogenetic trial project on the guidelines advocated by Samuel Hahnemann, MD, in Organon of Medicine, aphorisms 110−145,[8] CCRH (Central Council for Research in Homoeopathy, Government of India)[9] and ECH (European Committee for Homeopathy) guidelines.[10] The project was reviewed and approved on 16th September 2011, by Institutional Ethics Committee (Homeopathy India Pvt Ltd, Mumbai), constituted as per ICMR (Indian Council of Medical Research)[11] guidelines. The requirements regarding the obligations of investigators as per 'Guidance on Good Clinical Practice' as per ICH (International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Independent Ethics Committee) were complied with. The project was registered (Number: CTRI/2011/12/002314) with the Clinical Trials Registry − India (CTRI),[12] set up by the ICMR's National Institute of Medical Statistics (NIMS).

Investigations

Pre and post-drug-administration investigations included complete blood count, ESR (Erythrocyte Sedimentation Rate), HIV, Hep C screening (HCV-total antibody to hepatitis c virus), serum by EIS (30 method), blood biochemistry, urine routine analysis, pregnancy test, X-ray chest and electrocardiogram. Female volunteers were negative

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