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Mimosa humilis: A multicentric double blind Homoeopathic Pathogenetic Trial

Abstract

Objective: To elicit the pathogenetic response of the drug Mimosa humilis in homoeopathic potencies on healthy human beings. Methodology: Drug Mimosa humilis was proved through double-blind placebo-controlled method. The study was conducted at 2 centers. The drug was proved in two potencies (6C and 30C) on 16 apparently healthy volunteers who were selected after pre-trial medical examination by the specialists and after doing routine pathological investigations. The volunteers consumed 56 doses (04 doses per day for 14 days) of each potency in three phases (including 1" phase in placebo) for a varying period. The symptoms generated during the trial period were noted by the volunteers and elaborated and cross examined by the Proving Masters. The data obtained from both the centers was compiled at proving-cum-data processing cell at CCRH headquarters after de-coding. Observations: Out of the 10 provers who were on actual drug trial, 05 manifested symptoms. Drug was able to produce symptoms in each potency more or less on every part of the body. Some of the symptoms have been reproved which are mentioned in different literatures after fragmentary proving. Conclusion: Pathogenetic responses, elicited (new and reproved) during the proving trial will add to the literature available on the drug and benefit the research scholars and clinicians. This also needs verification through clinical trials.

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DRUG PROVING

Mimosa humilis : A multicentric double blind Homoeopathic Pathogenetic Trial

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***Objective*: To elicit the pathogenetic response of the drug *Mimosa humilis* in homoeopathic potencies on healthy human beings.**

***Methodology:* Drug *Mimosa humilis* was proved through double-blind placebo-controlled method. The study was conducted at 2 centers. The drug was proved in two potencies (6C and 30C) on 16 apparently healthy volunteers who were selected after pre-trial medical examination by the specialists and after doing routine pathological investigations. The volunteers consumed 56 doses (04 doses per day for 14 days) of each potency in three phases (including 1st phase in placebo) for a varying period. The symptoms generated during the trial period were noted by the volunteers and elaborated and cross examined by the Proving Masters. The data obtained from both the centers was compiled at proving-cum-data processing cell at CCRH headquarters after de-coding.**

***Observations:* Out of the 10 provers who were on actual drug trial, 05 manifested symptoms. Drug was able to produce symptoms in each potency more or less on every part of the body. Some of the symptoms have been reproved which are mentioned in different literatures after fragmentary proving.**

***Conclusion:* Pathogenetic responses, elicited (new and reproved) during the proving trial will add to the literature available on the drug and benefit the research scholars and clinicians. This also needs verification through clinical trials.**

Key words: homoeopathy; pathogenetic response; homoeopathic pathogenetic trial; drug proving; *Mimosa humilis*.

INTRODUCTION

The medicine *Mimosa humilis* was proved and introduced in homoeopathic literature by Dr. Mure Pathogen[1,2]. Mure says that the leaves of *M. humilis* close at least contact.[2]

A systematic proving of *Mimosa humilis* in homoeopathic potencies was necessary to get its pathogenetic power, so CCRH undertook its systematic Homoeopathic Pathogenetic Trial (HPT) as per the approved protocol.

Literature review

Botanical name : *Mimosa humilis* Linn.[1]

Natural Order : Leguminosae[1]

English : Sensitive plant[2]

Description

An annual shrub, stem 90 cm high, woody, ramose, pubescent above and covered with very sharp prickles. Leaves are bipinnate in pinnae being 3 or 4 paired, with small, linear folioles which close at the least contact, they vary from 6-12 on each side of the spike. The flowers are small sessile, forming pretty silky tufts of a violet colour. Fruit is somewhat triangular, flattened, covered with long and stiff hairs and surrounded by a persistent pericarp, divided in two capsules, each of which contains one seed.[1]

Distribution

Florida (U.S.A.), cultivated in India[1]

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Part used in Homoeopathy

Leaves.[2]

Objective

To elicit the pathogenetic response of the drug *Mimosa humilis* on apparently healthy human volunteers in homoeopathic potencies.

MATERIALS AND METHODS

Location and duration of study

The proving was conducted at Drug Proving Research Unit (Homoeopathy), Kolkata and at Drug Proving Research Unit (Homoeopathy), Ghaziabad in 2004-05.

Participants

16 apparently healthy volunteers from above mentioned two centers, between the age group of 18 to 50 years, comprising of 09 males and 07 females, were enrolled in this study. Pre-trial Medical Examination (PME) and Terminal Medical Examination (TME) of the volunteers were carried out by General Physicians, Psychiatrists, Cardiologists, Ophthalmologists, ENT Specialists, Dermatologists, Gynaecologists, Radiologists and their routine laboratory investigations at both the centers were done to ascertain their health status.

Drug

Mimosa humilis was procured in 6C and 30C potencies from M/s Hahnemann Publishing Co. Pvt. Ltd., India, in 100 ml. sealed phials of each dilution. Globules (number 30) were medicated with these attenuations at the headquarters office and sent to Drug Proving Units in coded phials (verum) along with placebo (control).

Placebo

Placebo was made up of plain globules (number 30) moistened with plain dispensing alcohol (unsuccussed). Thus placebo was made indistinguishable from verum.

Study Design

The study was a randomized double blind placebo controlled trial.

Methods

Before commencing the study, all provers were screened strictly on the basis of Inclusion and Exclusion criteria of "drug proving protocol" of CCRH.

Inclusion criteria includes:

1. The prover must be between 18-50 years of age, either male or female.
2. The provers should be apparently healthy. He/she should not show psychic or physical symptoms needing any kind of medical treatment. Pre-trial Medical Examination (PME) should confirm healthy status of the prover.
3. The prover must be intelligent enough to record the subjective symptoms generated by the drug during proving.

Exclusion criteria includes:

1. Persons suffering from any chronic disease or under any kind of medical treatment.
2. Hysterical or anxious persons, as such individuals display a high incidence of 'Placebo effects'.
3. Those who suffer from hypersensitivity diseases such as asthma, allergies and food hypersensitivities.
4. Pregnancy, puerperium or breast-feeding.
5. Colour blindness.
6. Age of less than 18 years, or more than 50 years.

'Written informed consent' from each volunteer was obtained before starting the proving. Pre-trial Medical Examination (PME) was conducted to confirm health status of the volunteers. Volunteers declared healthy were enrolled in the study. The study was conducted at two centers. According to CCRH Drug Proving Protocol, the sample size included 30% volunteers under control group at each center. So, out of 16 volunteers, 10 were kept on drug (verum) and 06 on placebo (control). All the volunteers were assigned code numbers and the coded drugs of different potencies (including placebo) were supplied in separate glass phials bearing code numbers of the respective volunteers; keeping both provers and proving masters blind about what provers were consuming (drug or placebo).

The study consisted of *three phases.* Each phase consisted of 56 doses of drug or placebo.

The volunteers were asked to take 4-6 globules of a particular potency of the coded drug, four times a day, dry on tongue.

The volunteers were instructed to daily note down the details of their feelings/changes in mind and body, after taking the coded drug/placebo in 'Prover's Day Book Proforma'.

- ***If sign(s) /symptoms(s) appeared:***

The volunteers were asked to stop taking the drug/placebo as soon as they felt any change or in case any sign(s) and/or symptoms(s) developed during the trial.

The volunteer noted down the sequence of the new sign(s) and/or symptoms(s), their progress and the number of doses after which such sign(s) and/or symptom(s) appeared with date, time of onset and duration for which they persisted. Intake of drug remained suspended till the sign(s) and/or symptoms(s) totally disappeared. Any change in normal routine of the prover with respect to daily habits diet, living conditions etc. or any treatment taken was also noted in the Prover's Day Book Proforma.

If the prover was experiencing the same symptom(s) what he/she had already shown, he/she was asked to stop the current quota and to switch over to the next quota after a washout period of 14 days.

After disappearance of sign(s) and/or symptom(s) produced by the drug, the volunteer was asked to wait for a further period of 07 days before taking the remaining doses of that potency, following the same dose schedule, as stated above. In case of further appearance of new sign(s) and/or symptom(s) or re-appearance of the earlier sign(s) and/or symptom(s), the same procedure was followed till the consumption of 56 doses of that potency by the volunteer.

Each prover was interrogated everyday by Proving Master about the appearance of new symptom(s) or progress of symptoms and was asked to note those in 'Symptom Elaboration Proforma' with respect to appearance and dis-appearance of symptoms, their location, sensation/character, modalities, concomitants, extension of symptoms, causation, clinico-pathological findings; other treatment taken.

- ***If no sign(s)/ symptoms(s) appeared:***

If no symptom was observed, the volunteers noted down 'No Symptom' with date and time of intake of the respective dose of the drug/placebo.

Before commencing the administration of subsequent potencies (subsequent Phase) of the drug, the volunteers were put on a rest period (it is a symptom free period between two phases of drug proving in which a volunteer does not take any drug) for 14 days and started taking next potency in the same procedure as mentioned above, till completion of 56 doses.

Same procedure was followed for the 3rd Phase.

Phase-I: It was a placebo phase. Its usefulness is that we get the prover's response to placebo and therefore acts as control for subsequent phases.

Phase-II: In 2nd phase, the proving was done with 30C potency.

Phase-III: In 3rd phase, the proving was done with 6C potency.

Each volunteer was interrogated by the Proving Master to verify the sign(s) and/or symptom(s) recorded by the volunteer. The symptoms recorded in 'Prover's Day Book Proforma' were verified by the Proving Masters and completed through further interrogation with the provers with respect to their location/ sensations/ modalities and concomitants, if any, in 'Symptoms Elaboration Proforma'.

During the course of proving, the volunteers were referred for specific laboratory investigation(s) to rule out any pathological cause of appearance of symptom(s). Such laboratory tests were performed to identify any correlation between the subjective and objective changes during the course of proving. The expert opinion of the honorary consultant(s) was obtained, wherever needed.

After completion of trial of all potencies, the volunteers were examined by the specialists again. This is called 'Terminal Medical Examination' (TME).

On completion of all the respective phases of the proving, the compilation of data recorded in 'Prover's Day Book Proforma', 'Symptoms Elaboration Proforma', 'Pathological Report Sheets' and 'Terminal Medical Examination sheets', was done at the Council headquarters by the Drug Proving-cum-Data Processing Cell. After decoding, the sign(s) and/or

symptom(s) generated by the volunteers kept on the drug were separated from those generated by the volunteers kept on placebo. The sign(s) and/or symptom(s) which were common to both the groups i.e. placebo as well as drug groups were not taken into consideration while compiling the symptomatology of the drug.

Management of adverse effects – A vial of antidote is sent with each quota to each center. In this trial homoeopathic potencies of Camphor were used as Antidote as it is believed that Camphor can antidote nearly every vegetable medicine.[3] The Proving master gives antidote to the volunteer if symptoms continue for a long time or intensity is much to cause discomfort. He is also directed to take advice of honorary consultants and to get laboratory investigations done, if required.

Pathogenetic effects

Pathogenetic effects (Proving symptoms) are defined as all changes in clinical events and laboratory findings reported by the volunteers during a Homoeopathic Pathogenetic Trial and recorded in the final report. The incidence of pathogenetic effects per volunteer is defined as the total number of findings observed in the trial divided by the total number of provers. So incidence in this proving was 1.3 findings per volunteer.

Pathogenetic effects were deduced

(i) from comparison of symptoms developed in placebo phase with symptoms during intervention phases (Intraprover comparison);

(ii) from comparison of symptoms developed by provers on control (for all three phases) with provers on actual drug trial (interprover comparison).

Results

At Drug Proving Research Unit (DPRU), Kolkata, out of 05 volunteers, 04 volunteers reported symptoms. At Drug Proving Research Unit (DPRU), Ghaziabad out of 05 volunteers, 01 volunteer reported symptoms consequent upon the administration of the drug.

The following symptoms were observed during the drug proving

- In the first parenthesis, the 1st number given after every symptom denotes number of volunteers produced that particular symptom and 2nd number denotes potency used.
- In second parenthesis, the 1st number denotes number of doses after which symptom produced that particular symptom and the 2nd number denotes the duration for which the symptom lasted in days.
- Symptoms produced during the pathogenetic trial of the drug were compared with the homoeopathic literature cited in the reference and those symptoms which were found in the literature, are shown in **bold**, superscribed with a numerical that refers to the respective literature.

Head

- **Pain in head**[4] like hammering, *amel.* by massage. (1, 30C), (32,5)
- Severe pain in temporal region on both sides; can't open eyes due to pain, *amel.* by pressure. (1,30C), (31,2)
- Throbbing pain in vertex, *agg.* afternoon and during bath. (1,6C), (18,1)

Nose

- **Coryza**[2,4,5]
- **Sneezing**[2,4,5] frequent, throughout the day (1,6C), (52,4)

Throat

- Dryness of throat, desire for drinking cold water. Difficulty in drinking water. Irritation in throat. (1, 30C), (32,5)

Rectum

- **Constipation**[4]; stool hard and passes after great straining. (1, 6C), (51,3)

Urethra

- Frequent urination, burning sensation during and after urination (1,6C), (5,12)

Urine

- Urine yellow, offensive and profuse. (1,6C), (5,12)

Extremities

- Itching eruptions of red colour on both forearms. (1, 6C), (54,4)

- **Pain in leg** [2,4,5] (right) started from waist goes to foot. Pain, *agg.* by keeping foot on floor, *amel.* by massage and warm application. (1, 6C), (26,2)

Fever

- Fever worse at noon with severe bodyache and thirst for water in small quantity at short intervals. Fever before and during menses. (1,30C), (32,5)
- Feverish feeling with coryza. (1,6C), (52,4)

Discussion

The drug was able to produce symptoms in 6C and 30C potencies. Five symptoms were reproved which are already in the available literatures. Twelve symptoms were produced by the volunteers of verum group in 2nd or 3rd phases.

The drug seems to be indicated in headache, coryza and fever. Drug has also shown affinity for constipation with hard stool. It also produces frequent, burning urination. These symptoms may help in clinical application of the medicine.

Conclusion

The symptoms appeared (new and re-proved) during the trial will add to the available literature on this medicine and benefit the research scholars and clinicians. These symptoms need further verification through clinical application in different settings.

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