Indian Journal of Research in Homoeopathy
Vol. 4, No. 4, October-December 2010

DRUG PROVING

# Ocimum sanctum-A multicentric double blind homoeopathic pathogenetic trial

Rajpal[1], Vinay Kr. Singh[1], R.K. Roy[2], C.P. Chaudhary[2], P.C. Mal[3], A.K. Bhakat[3]

[1]Central Council for Research in Homoeopathy, New Delhi, India
[2]Drug Proving Research Unit (H), Ghaziabad, Uttar Pradesh, India
[3]Drug Proving Research Unit (H), Midnapore, West Bengal, India

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

***Methodology:*** Drug *Ocimum sanctum* was proved by the Central Council for Research in Homoeopathy (CCRH) through double-blind placebo-controlled method. The study was conducted at two centers. The drug was proved in three potencies (6C, 30C and 200C) on 28 apparently healthy volunteers who were selected after conducting pre-trial medical examination by the medical specialists and routine laboratory investigations. In the first phase volunteers were given 56 doses (04 doses per day for 14 days) of placebo. In the next three phases 56 doses (04 doses per day for 14 days) of each potency or placebo were consumed. The symptoms generated during the trial period were noted by the volunteers and elaborated 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 18 provers who were on actual drug trial, 10 manifested symptoms. Drug was able to produce symptoms in each potency more or less related to every part of the body. Some of the symptoms have been reproved which are mentioned in different literatures after the fragmentary proving.

***Conclusion:*** New and reproved pathogenetic responses elicited during the proving trial expands the scope of use of the drug *Ocimum sanctum* and will benefit the research scholars and clinicians. These symptoms will carry more value when verified clinically.

***Keywords:*** homoeopathy; pathogenetic effect; homoeopathic pathogenetic trial; drug proving; ocimum sanctum.

## Introduction

Since ancient times, this plant is known to have medicinal properties. The aqueous extract of leaves of *Ocimum sanctum* showed the significant reduction in blood sugar level in both normal and alloxan induced diabetic rats. Significant reduction in fasting blood glucose, uronic acid, total amino acid, total cholesterol, triglyceride and total lipid indicated the hypoglycemic and hypolipidemic effects of tulsi in diabetic rats. Renal glycogen content increased 10 fold while skeletal muscle and hepatic glycogen levels decreased by 68 and 75% respectively in diabetic rats as compared to control. This plant also showed antiasthemitic, antistress, antibacterial, antifungal, antiviral, antitumor, gastric antiulcer activity, antioxidant, antimutagenic and immunostimulant activities.[1]

According to a study *Ocimum sanctum* has shown protective effect on different regions of brain against the detrimental effect of restraint stress.[2]

*Ocimum sanctum* or the Holy basil is a well known small herb in India. It is a highly sweet-scented plant and is considered by the natives of India to be of great value as it is connected with all the religious ceremony of Hindus.[3]

It is demulcent, expectorant and anti periodic. Root is febrifuge; seeds are mucilaginous and demulcent. Dried plant is stomachic and expectorant. Leaves are anti-catarrhal, expectorant, fragrant and aromatic. Infusion of the leaves is given in malaria and as a

** Address for Correspondence:*
*Dr. Rajpal, Asstt. Director (H)*
*Central Council for Research in Homoeopathy*
*61-65, Institutional Area, Janakpuri, New Delhi- 110 058*
*Email: ccrhdp@yahoo.com*

stomachic in gastric diseases in children and in hepatic affections. Persons affected with bad skin diseases such as itches, ringworm, leprosy, bad blood etc., should drink the juice of basil leaves and also apply the same by itself or preferably mixed with juice of lemon (lime-juice) as a paste for radical cure. Dried plant in decoction (1 in 10) is a domestic remedy for croup, catarrh, bronchitis and diarrhoea. Dried leaves are used as snuff in myiosis and ozoena. Leaf juice poured into the ear is a first rate remedy for earache. Fresh juice checks vomiting and destroys intestinal worms. Root in decoction is used in febrile affections.[4]

*Ocimum canum* is a species of this shrub which grows abundantly in Brazil. Dr. Mure proved and introduced this remedy into Homoeopathy. *Ocimum sanctum* is the black variety of the herb. Drs. Pramada Prasanna Biswas of Pabna, Bengal, N. Sinha and N.C. Ghosh have made provings of this drug.[3]

However, a systematic proving of *Ocimum sanctum* in homoeopathic potencies was necessary to elicit its pathogenetic power, so Central Council for Research in Homoeopathy undertook its systematic Homoeopathic Pathogenetic Trial (HPT) as per the approved protocol.

| | | |
|---|---|---|
| **Botanical Name** | : | *Ocimum sanctum* Linn.[5] |
| **Family** | : | Labiatae[5] |
| **Common names** | : | |
| *Hindi* | : | Kala tulsi |
| *English* | : | Holy basil |
| *Sanskrit* | : | Vishupriya, Divya, Bharati[1] |
| *French* | : | Basilic Saint[4] |

## Description

A much branched herb, 30 to 90 cm high, sometimes woody at the base. Stem and branches clothed with glandular hairs. Leaves 2.5 to 5 cm long, oblong or elliptic oblong, obtuse or acute, entire or subserrate, hairy on both surfaces and minutely dotted, petioles 1.25 to 2.5 cm long; racemes slender, 15 to 20 cm long, bracts not exceeding the calyx, broadly ovate or cordate ovate, acuminate ciliate; pedicles slender, as long as or longer than the calyx, 4 mm long purplish pink; upper pair of stamens with a small bearded appendage at the base. Nutlets broadly ellipsoid, smooth yellow dotted with black.[5]

## Distribution

This small herb is found throughout India and cultivated near houses and temples of Hindus.[4]

## Part used in Homoeopathy

Whole plant excluding roots.[5]

## Potencies used

6C, 30C & 200C

## Objective

To elicit the pathogenetic response of the drug *Ocimum sanctum* 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), Midnapore and at Drug Proving Research Unit (Homoeopathy), Ghaziabad in 1996-97.

### Participants

Total 28 apparently healthy volunteers from above mentioned two centers, between the age group of 18 to 50 years, comprising of 18 males and 10 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. After recommendation of experts, healthy volunteers were enrolled in the Homoeopathic Drug Proving Programme.

### Drug

*Ocimum sanctum* was procured in 6C, 30C and 200 C potencies from M/s. Hahnemann Publishing Co. Pvt. Ltd., Kolkata, India, in 100 ml. sealed phials of each dilution. Globules (number 30) were medicated with these attenuations at the Council's headquarters office and sent to Drug Proving Research 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) and was therefore 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 by the experts and apparently healthy provers between the age group of 18-50 years, both males and females were included in the drug proving trial. Pregnant and lactating mothers were excluded.

'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 28 volunteers, 18 were kept on drug (verum) and 10 were on placebo (control) in all four phases. 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 four phases. Each Phase consisted of 56 doses of drug or placebo.

*Phase-I:* Placebo phase. It is useful in generating prover's response to placebo and therefore symptoms generated by the prover in this stage act as control for subsequent phases.

*Phase-II*: In 2$^{nd}$ phase, the proving was conducted with 200C potency.

*Phase-III*: In 3$^{rd}$ phase, the proving was conducted with 30C potency.

*Phase-IV*: In 4$^{th}$ phase, the proving was conducted with 6C potency.

### Procedure of proving

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

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

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

The volunteer noted down the sequence of the appearance of new sign(s) and/or symptoms(s), their progress and the number of doses after which such sign(s) and/or symptoms(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 in respect of daily habits pertaining to diet, living conditions etc./any treatment taken was also noted in the Prover's Day Book Proforma.

After disappearance of sign(s) and/or symptom(s) produced by the drug, the volunteer had 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), the same procedure as stated above was followed till the consumption of 56 doses of that potency by the volunteer.

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.

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

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

If no symptom was observed, the volunteers noted down as '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 remained on a washout / rest period (it should be a symptom free period between two phases of drug proving in which a volunteer does not take drug) for 14 days and started taking next potency in the same procedure as mentioned above, till completion of 56 doses.

The same procedure was followed for the 3rd and 4th phases.

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 Master and completed through further interrogation with the provers in 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). Since 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 underwent 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's 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.[6] Proving master gives antidote to the volunteer if symptoms continue for a long time or intensity is much to cause discomfort. Proving Master 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.[7] So incidence in this proving was 1.77 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 for phases) with provers on actual drug trial (Interprover comparison)

- 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.

## Results

At Drug Proving Research Unit (DPRU), Midnapore, out of 13 volunteers, 04 volunteers reported symptoms. At Drug Proving Research Unit (DPRU), Ghaziabad out of 15 volunteers, 06 volunteers reported symptoms consequent upon the administration of the drug.

The following symptoms were observed during the trial:

### Mind

- Emotional mood changing to a pleasing and cheerful mood; feeling of love and bliss. Likes to be absorbed in bliss; feeling as if full of energy. Thinking of beautiful nymph, embracing and doing intercourse, *agg.* when alone. (1,200C), (25,20)
- Depressed; anxious of future as how he would pass the examination. **Concentration difficult**[3], hypochondriac mood, *agg.* while trying to read and concentrate. (1, 30C), (48,5)

### Vertigo

- Feeling of reeling with headache (1,30C) (32,11)

### Head

- **Throbbing pain**[3] in both temples, *agg.* stooping, ***amel.*** **pressure**[3], lying down (1,200C), (24,1), (50,1)
- Falling of hairs with itching of scalp (1,30C),(25,4),(35,4)
- Small eruptions on forehead with itching and pricking sensation, *agg.* applying soap (1,30C), (25,3)
- Heaviness of head (1,30C) (19,3)

### Eyes

- Stye on right upper eyelid, painful, *agg.* closing eyes, reading. Discharge of little pus from stye later. (1,200C), (43,1)
- Pain and swelling in left upper eyelid (1,30C), (28,4)

### Nose

- **Watery discharge from nose**[3] (1,6C & 200C), (41,1), (36,1)

### Face

- Pain and tenderness of upper part of eyebrows (1,30C), (32,11)

### Mouth

- **Aphthae in mouth and on tongue**[3] with burning pain, *agg.* while eating (1,200C), (25,3)

### Throat

- **Pain**[3] and soreness in throat, **difficulty in deglutition**[3] *amel.* after warm drink (1,6C), (12,4)

### Stomach

- Impaired appetite (3,30C, 200C), (32,11), (48,5), (10,5)
- Thirst increased (1,30C), (41,1)
- Thirst during fever (1,30C), (16,10)

### Abdomen

- Stitching and pulsating pain in left hypochondrium, *agg.* by motion *amel.* after taking rest (1,30C), (49,3)
- Pain in abdomen, above umbilicus, *agg.* by motion, *amel.* after sitting, lying down (1,6C), (40,1)
- Pain in abdomen, above umbilicus, *agg.* on walking, *amel.* by pressure (1,200C), (33,1)
- Pain in lower abdomen (1,200C), (46,3)

### Stool

- Hard, lumpy, scanty, blackish stool (1,200C), (33,1)
- Unsatisfactory stool (1,30C), (32,11)

### Female

- **Leucorrhoea profuse, white, thick, bland discharge (1,30C)**

### Cough

- Cough with white expectoration and pain in abdomen, *agg.* at night (1,30C), (41,3)

### Sleep

- Disturbed sleep (1,30C), (48,5)

### Fever

- **Fever with pain in legs and fatigue**[3] (1,30C), (31,1)
- Feverish (1,30C), (10,5)
- **Feverish with pain all over**[3] (1,200C), (20,1)
- Fever with drowsiness and loss of appetite (1,6C), (16,1)

### Skin

- Red rashes all over the body, burning pain after itching (1,30C), (32,15)

### Generalities

- Aching pain all over body (1,6C), (12,4)
- Discomfort, aching pain, dullness, lack of energy, aversion to work with feverish feeling (1,30C), (48,5)

## Discussion

Drug was able to produce symptoms in 6C, 30C and 200C potencies. Five symptoms were reproved which are already in the available literature. Thirty two symptoms were produced by the volunteers on verum group in 2nd, 3rd or 4th phases.

According to *Charaka, Harita, Chakradatta, Bangasena,* and others have found *Ocimum sanctum* very efficacious in cough, cold, catarrh, fever and constipation and all these symptoms are produced during the pathogenesis of the drug. Mind symptoms can be compared with *Cocculus indicus* and *Platina*. Only one symptom i.e. impaired appetite is produced in 2 provers. The drug seems to be indicated in headache, stye, coryza, aphthae, impaired appetite, abdominal pain, cough and fever. Drug has also produced symptoms like unsatisfactory stool and hard, lumpy, blackish stool. 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 proved symptoms need further verification through clinical application in different settings.

## Acknowledgements

The authors are grateful to Prof. (Dr.) C. Nayak, Director General, CCRH headquarters, for his persistent encouragement and enthusiastic support for the preparation of the article. We also acknowledge Late Dr. D.P. Rastogi, former Director CCRH, under whose guidance the proving was conducted.

## References

1. Modak Manisha et al. Indian Herbs and Herbal Drugs Used for the Treatment of Diabetes. *J Clin Biochem Nutr.* 40(3) 2007 May: 163–173.
2. Tabassum I, Siddiqui ZN, Rizvi SJ. Protective effect of *Ocimum sanctum* on lipid peroxidation, nucleic acids and protein against restraint stress in male albino rats. *Biology and Medicine.* Vol 1 (2) 2009: 42-53.
3. Ghosh SC. Drug of Hindustan, 9th Edition. M/s. Hahnemann Publishing Co. Pvt. Ltd., Kolkata, 2007:247-256.
4. Nadkarni KM. Indian Materia Medica, Vol-I. Bombay Popular Prakashan, Mumbai, 1991:865-866.
5. Govt. of India, Ministry of Health and Family Welfare, Homoeopathic Pharmacopoeia of India, Vol-I. The Controller of Publication, New Delhi, 1971:156-157.
6. Allen HC. Allen's Key Notes and Characteristics with comparisons of the leading remedies of the Materia Medica with Nosodes, 8th Edition. M/s B. Jain Publishing (P) Ltd., New Delhi, 1997:78.
7. Dantas F, Fisher P, Walach H. et. al. A systematic review of the quality of homeopathic pathogenetic trials published from 1945 to 1995. *Homeopathy.* 96 (1), 2007 Jan: 4-16.