

## ORIGINAL ARTICLE

# A multicentric, double-blind randomized, homoeopathic pathogenetic trial of *Allium sativum*

Raj K. Manchanda<sup>1</sup>, Anil Khurana<sup>1</sup>, Raj Pal<sup>2</sup>, Bhopal Singh Arya<sup>3</sup>,  
Anil Kumar Vichitra<sup>3</sup>, P. G. Mohanan<sup>4</sup>, Pritha Mehra<sup>3\*</sup>, Shilpa Sharma<sup>1</sup>, Vinay K. Singh<sup>3</sup>

### ABSTRACT

**Background:** Homoeopathic drug proving is an integral part of Homoeopathic System of Medicine. It is the first step in finding out the pathogenetic powers of a drug.

**Objective:** To elicit the pathogenetic response to *Allium sativum* in homoeopathic potencies on healthy human provers.

**Materials and Methods:** A multi-center randomized, placebo-controlled, double-blind trial was conducted at two centers of the Central Council for Research in Homoeopathy (CCRH). Proving was conducted on 33 healthy provers after the pretrial medical examination. All the provers were given 12 doses of placebo divided in 4 doses/day for 3 days during the first phase of the trial. After randomization, in the intervention group (21 provers), *Allium sativum* (*A. sativum*) was proved in 6C and 30C potencies, in two phases. In the placebo group, 12 provers were administered placebo in the same manner. The symptoms manifested during the trial period were noted down by the provers and then elaborated by the proving masters. The generated data on *A. sativum* were then compiled and analyzed at proving-cum-data processing cell at CCRH headquarters.

**Results:** Out of 21 provers who were on actual drug trial, only nine provers manifested symptoms. Drug was able to manifest symptoms in both the potencies, in more or less every part of the body.

**Conclusion:** The pathogenetic response elicited during the proving trial expands the scope of use of the drug *A. sativum* and will benefit the research scholars and clinicians. The generated symptoms of this drug will carry more value when verified clinically.

**Keywords:** *Allium sativum*, Double blind, Drug proving, Homoeopathic pathogenetic trial, Homoeopathy, Pathogenetic effect, Placebo

### INTRODUCTION

*Allium sativum* L., commonly known as garlic, is one of the key ingredients of spices used in every house. Its medicinal properties have been known since ancient

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<sup>1</sup>Central Council for Research in Homoeopathy, New Delhi,  
<sup>2</sup>Homoeopathic Treatment Center, Safdarjung Hospital, New Delhi,  
<sup>3</sup>Nodal Office and Center for Drug Proving Research Study, Dr. D. P. Rastogi Central Research Institute (H), Noida, Uttar Pradesh,  
<sup>4</sup>Center for Drug Proving Study, Central Research Institute (H), Kottayam, Kerala, India

**\*Address for correspondence:**

Dr. Pritha Mehra,  
Dr. D. P. Rastogi Central Research Institute (H), A 1/1, Sector 24, Noida, Uttar Pradesh, India.  
E-mail: [ccrhdhp@gmail.com](mailto:ccrhdhp@gmail.com)

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times. It was used for dressing wounds during the First World War. In the 16<sup>th</sup> century B.C., the Egyptians used it in about 22 remedies for various ailments such as heart diseases, tumors, and insect bites etc. Wealthy Romans but gave it to their soldiers to make them strong. In today's world, it is used as an antibiotic, expectorant, antidiabetic, and as an aid for expelling worms, reducing blood clotting, and lowering blood pressure. It is used in treating the infections, for example, bronchial and digestive. It is administered as a circulatory remedy and in diabetes.<sup>[1]</sup>

Hippocrates warned that garlic "causes flatulence," a feeling of warmth on the chest and a heavy sensation in the head. In 1955, a Russian study found that garlic extracts bind heavy metals, thus aiding their elimination.<sup>[2]</sup>

It is used in Ayurveda, Unani.<sup>[3]</sup> It is known for its pungent, heating, oleaginous, tonic, aphrodisiac, fattening, digestive, and antihelminthic effects. appetizer, sharp taste, diuretic, carminative, alexipharmic effects. It is found to be useful in diseases of the eye, heart, low fevers, bronchitis, inflammation, piles, leucoderma, asthma, "vata," lumbago, tumors, epileptic fits, thirst, and earache, inflammation, paralysis, pain in the body and joints, troubles of the spleen, liver, and lungs. chronic fevers, caries of the teeth, and thins the blood.

In Cambodia, the leaves are used in the treatment of asthma.<sup>[3]</sup> Chinese have reported in their trial that garlic can be successfully used for cryptococcal meningitis.<sup>[2]</sup> has anticarcinogenic activity, antitubercular activity against *Mycobacterium tuberculosis in vitro* and *in vivo*. antibacterial activity against shigellosis anti-atherosclerosis activity, hepato-protective activity and antidiabetic effect. Handling of garlic for cooking causes contact dermatitis.<sup>[4]</sup> Garlic also demonstrated ameliorative effects in acute lepromatous neuritis.<sup>[5]</sup>

Toxicity studies of garlic extract and garlic oil revealed a significant rise in urea and alkaline phosphatase in serum.<sup>[4]</sup> The signs and symptoms of acute overdose of garlic as herbal medicine includes dizziness, light-headedness, burning sensation of mouth, haematoma, nausea, sweating, leukocytosis, anorexia, diarrhea, emesis, and menorrhagia. It can exacerbate bleeding in patients taking aspirin or anticoagulants.<sup>[2]</sup>

Garlic as a drug, "*Allium sativum*" was introduced in Homoeopathic Materia Medica proved in France by Petroz and Teste, 1852.<sup>[6]</sup> Homoeopathic drug proving is an integral part of Homoeopathic system of medicine. This is the first step in finding out the pathogenetic powers of a drug. As the extensive proving of this drug have not been done therefore, a systematic homoeopathic pathogenetic trial (HPT) of the drug in homoeopathic potencies to elicit its pathogenetic power was carried out by the Central Council for Research in Homoeopathy (CCRH) at two of its centers as per the approved protocol.

### Description

An acaulescent, bulbous, hardy perennial herb, cultivated as an annual, up to 60 cm in height. Bulbs ovate, flattened below, tapering upward and compound, i.e. composed of small bulblets. Stem much reduced (disc), convex-conical, internodes very compressed from where fleshy scale leaves arise, a bud present at the apex from which flowering scape develops. Leaves are linear, flat, lanceolate, scape slender, spathe one-leaved, long, pointed, head-bearing bulbs, and flowers in umbel. Flowers small, white; perianth trimerous with six petals, segments lanceolate, acuminate; stamens six, filaments of inner whorl tricuspidate; ovary trigonous, trilocular, style filiform. Fruit is a capsule.<sup>[7,8]</sup>

Botanical Name : *Allium sativum* L.

Family<sup>[2]</sup> : Alliaceae (Liliaceae)

Order : Asparagales

Common names<sup>[3,5]</sup>

Hindi : Lasan

Sanskrit : Arishtha, Bhutabhna, Dirghapatraka

Bengali : Rasun

Tamil : Vellaipundu

English : Garlic, Churl's Treacle, Poor man's treacle

Arabic : Saum, Taum

Chinese : Suan, suan T'euou, Ta Suan

German : Knoblauch, lauch

Chemical : Volatile oil (e.g. allyl alcohol, alliin, alliinase, allicin), scordinins

Constituents<sup>[1,2]</sup> : Selenium, Sulphur, and Selenium-containing compounds, Vitamins A, B, C, and E.

Distribution: Native of Mediterranean region, cultivated universally<sup>[7,8]</sup>

Part used: Mature bulbs.<sup>[7,8]</sup>

## MATERIALS AND METHODS

### Study Design and Study Setting

A randomized, double-blind, placebo-controlled study was conducted at the Central Research Institute (Homoeopathy), Kottayam and Central Research Institute (Homoeopathy), Noida.

### Subjects

*Selection of provers:* Applications were invited from 15 to 20 volunteers of both sexes and age 18 years and above through “notice” placed on the notice board of the institutes and homoeopathic colleges. The volunteers of non-homoeopathic background were also considered for the study. Pretrial medical examination (PME) was then conducted for all the volunteers after getting written informed consent from them. Detailed physical, pathological, and radiological examinations were conducted by the medical experts to ensure the health status of the volunteers.

### Inclusion Criteria

- Age: 18 years and above
- Sex: Both male and female
- Health status: Experts acceptance and certifying the volunteer is healthy
- Volunteer must be 2 months clear of any homoeopathic medicine and no change in health status in last 3 weeks
- Volunteer to be intelligent enough to record carefully the facts, subjective, and objective symptoms generated by the drug during proving.

### Exclusion Criteria

- Volunteers suffering from any acute or chronic disease
- Volunteers under any kind of medical treatment
- Hysterical or anxious persons

- Women during pregnancy, puerperium, and while breast-feeding
- Persons with color blindness
- Persons having addictions
- Persons who has undergone surgery in the last 2 months
- Participation in another clinical or proving trial during the last 6 months.

The volunteer declared healthy by the medical experts were then enrolled as a prover. For the pathogenetic drug trial of *Allium sativum*, a total of 33 volunteers (medical students) were enrolled as provers.

### Sample size

According to the drug-proving protocol of the Council, there should be at least 15 provers at one center, 30% of whom will act as control. Therefore, out of 33 provers, 21 were on verum and 12 were on placebo of both these centers. [Figure 1]

### Proving Symptoms

The sign(s) and/or symptom(s) generated by verum(drug) or placebo (control) on each prover are noted down with stage, number of doses after which each of the signs or symptoms appeared, and the duration for which they persisted. The sign(s) and/or symptom(s) generated by verum group are separated from those generated by provers of control group. The sign(s) and/or symptom(s) which were produced by the placebo as well as the drug in provers are not taken into consideration.

### Classification of Symptoms

- RS: Recent symptoms, i.e. a symptom that you are suffering from now or have been suffering from in the last year
- NS: New symptom

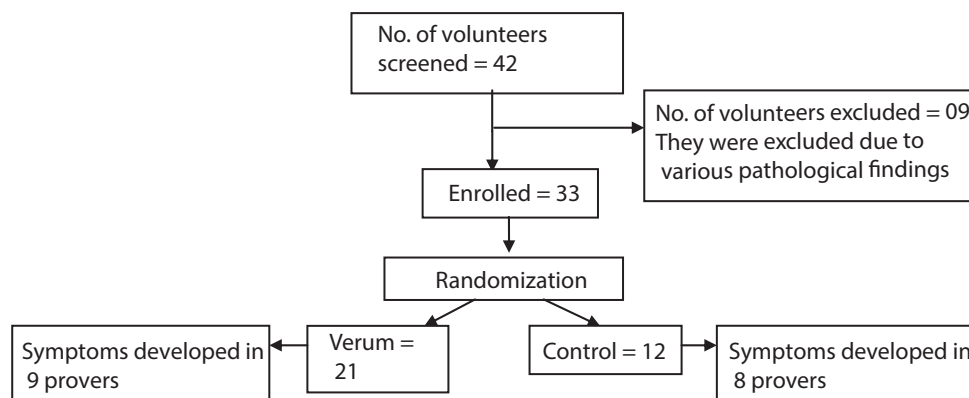


Figure 1: Flow chart of study participants

- OS: Old symptom. State when the symptom occurred previously
- AS: Alteration in present or old symptom (e.g. used to be left side, now on the right side)
- US: An unusual symptom.

### Duration of Study

Proving period: One year (2011–2012).

### Ethics and Consent

The Council's Ethical Committee approved the study protocol. Proving masters with experience in drug proving were sensitized about the protocol. Written informed consent was received from all the volunteers prior to enrollment in the study.

### Procedure

The study was conducted in three phases at each of the centers. In each phase, 12 doses of drug or placebo as per randomization were administered, divided in 4 doses/day for 3 days (if no symptom arises).

1. Phase I: Placebo phase. All the provers were given placebo in Phase I. It is useful in generating prover's response to placebo in both the groups and therefore symptoms generated by the prover in this stage act as control for subsequent phases
2. Phase II: In 2<sup>nd</sup> phase, the verum group received the drug in 6C potency and placebo group received optically identical placebo
3. Phase III: In 3<sup>rd</sup> phase, the verum group received the drug in 30C potency and placebo group received optically identical placebo.

At each study center, a proving master supervised the volunteers enrolled in the study. After receiving the informed consent, PME, the baseline characteristics equivalent to homoeopathic interview, and the findings with respect to all the systemic examination and laboratory investigations were filled in the Proforma. The volunteers were instructed to take four globules of the coded drug 4 times a day for 3 days maximum. The provers were asked to note down daily the details of their feelings/changes in mental and/or physical level, after taking the coded drug in "Prover's Day Book Proforma."

### If Sign(s)/Symptoms(s) Appeared

- The provers 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 provers 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

- 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 30 days (washout period) before starting the next phase following the same dose schedule as stated above.

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(s), sensation(s), modalities and concomitants, extension of symptoms, causation, clinico-pathological findings, and other treatment taken, if any, in "Symptoms Elaboration Proforma."

During the course of proving, the provers 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.

### If No Sign(s)/Symptoms(s) Appeared

The provers noted down "no symptom" with date and time of intake of the respective dose of the drug/placebo in "Prover's Day Book Proforma."

Before commencing the administration of subsequent potencies (subsequent phase) of the drug, the provers remained on a washout/rest period for 30 days and started taking next potency following the same procedure as mentioned above, till completion of all the doses/appearance of symptom. The same procedure was followed for the 3<sup>rd</sup> phase. After completion of trial of all potencies, the provers underwent terminal medical examination (TME).

On completion of all the phases of the drug proving, the compilation of data recorded in "Prover's Day Book Proforma," "Symptoms Elaboration Proforma," "Pathological Report Sheets," and "TME sheets" was done by the drug proving-cum-data processing



cell at the Council's headquarters. After decoding, the sign(s) and/or symptom(s) generated by the provers kept on the drug were separated from those generated by the provers kept on placebo.

### Randomization and Blinding

Provers were randomized in two groups, Group I ( $n = 21$ ): Homoeopathic group and Group II ( $n = 12$ ): Placebo group. Random numbers were generated with the help of computer-based software available at <http://www.randomizer.org> (accessed in August 2011) and the random code was kept at CCRH headquarters. The decoding of the group was done after the compilation of the symptoms produced in both the groups.

Both homoeopathic drug and placebo were made in identical form so indistinguishable. Provers and the investigators were kept blinded to the group allocation and also to the identity of the drug. All the provers were assigned code numbers, and coded drugs of different potencies were supplied in separate glass phials, bearing code numbers of the respective prover.

### Intervention

#### Homoeopathic group

About 100 ml sealed bottles of *A. sativum* in 6C and 30C were procured from a GMP-certified homoeopathic drug manufacturer in India. Globules of number thirty were medicated with these attenuations at the CCRH headquarters office.

#### Placebo group

Placebo was made up of un-medicated globules (number thirty) moistened with un-medicated dispensing alcohol (unsuccussed) and was therefore indistinguishable from *Verum*.

### Management of Adverse Effects

A vial of medicated globules of *Camphora* 30C was sent with each quota to each center as "antidote" as it is believed to antidote nearly every vegetable medicine.<sup>[9]</sup> In case of prolonged or intensely disturbing symptoms, antidote was to be used by the proving master after consulting the medical expert.

### Statistical Analysis

Statistical analysis was done by using IBM SPSS 20.0. Comparison between Homoeopathy and placebo groups were performed at baseline to assess randomization effect using independent "t-test" for continuous variables and Chi-square test for categorical variables. Changes from the PME to TME in the pathological variables

of body mass index (BMI), haemoglobin (Hb), erythrocyte sedimentation rate (ESR), fasting blood sugar (FBS), total cholesterol, serum urea, serum glutamate oxaloacetate transferase (SGOT), and serum glutamate pyruvate transferase (SGPT) were calculated by independent "t-test." In all the analyses,  $P < 0.05$  was considered significant.

### Pathogenetic Effects

Pathogenetic effects (proving symptoms) are defined as all changes in the state of health and laboratory findings reported by the provers during the HPT and recorded in the final report. The incidence of pathogenetic effects per prover is defined as the total number of findings observed in verum group of the trial divided by the total number of provers.<sup>[10]</sup>

Pathogenetic effects were deduced from:

- i. Comparison of symptoms developed in placebo phase with symptoms during intervention phases (intraprover comparison)
- ii. Comparison of symptoms developed by provers on control (for all phases) with provers on actual drug trial (interprover comparison).

## RESULTS

A total of 33 healthy provers were enrolled. Out of whom, 30 provers underwent the Terminal Medical Examination (TME). 2 and 1 prover(s) were dropped out from the verum and placebo group respectively. Thus the data analysis was done on 30 provers. The flow of the patients in the study is given at figure 1. the baseline information in both the groups were comparable [Table 1]. Though there was difference in FBS at baseline between the groups but they were within normal limits.

During the pathogenetic trial, out of 21 provers who were in verum group, only 9 (42.85%) provers reported symptoms consequent upon the administration of the drug. In the placebo group, 8 (66.67%) provers reported the incidence of symptoms. The Chi-square test shows that there is no difference between the 6C and 30C groups for producing the symptoms ( $P = 0.068$ , confidence interval:  $-0.68$  to  $-0.019$ ). The symptoms were observed from both the potencies, i.e. 6C and 30C. Out of 23 symptoms which were produced by the provers of verum group in 2<sup>nd</sup> and 3<sup>rd</sup> phases, 14 symptoms were produced in 6C potency [Table 2] whereas nine symptoms were produced in 30C potency [Table 3].

The present study shows that there is no statistically significant difference between the pathological variables of Hb, ESR, FBS, total cholesterol, blood urea, SGOT, and SGPT in the PME and TME of the verum and placebo groups. In BMI, mean changes occurred in the verum group from PME at  $20.7 \pm 2.8$  to  $20.8 \pm 2.9$  at TME and in control group from PME at  $23.2 \pm 4.3$  to  $23.3 \pm 4.2$  at TME. In verum group, Hb values decreased from  $12.5 \pm 1.5$  to  $11.9 \pm 1.3$  and in control group, changes noticed from PME at  $13.3 \pm 1.8$  to

$12.7 \pm 1.6$  at TME. Statistically, there is no difference between PME and TME in BMI and Hb [Table 4].

Intragroup analysis was done considering the physical built, physical generals, and mental generals of the provers in verum group who have produced symptoms, but no significant similarities were found in these provers. Further, intergroup analysis considering the above parameters was done in the provers who have produced symptoms in the verum group and control group. There were no significant similarities or dissimilarities found.

A comprehensive qualitative symptom profile of intervention group, control group, and former homoeopathic-proving symptoms found in literature<sup>[11-13]</sup> [Table 5] reflect that:

- No symptoms were generated in intervention group in regional spheres of mind, eye, ear, mouth, teeth, throat, rectum, and skin in the present study, although they are present in the literature
- In present and previous proving, the common regional affinities were found in head, nose, face, stomach, abdomen, chest, back, extremities, and generalities.

The number of symptoms developed in control (placebo) group was almost 3 times of those produced in the verum group. Some of the symptoms are different from those developed in verum group and few are overlapping. No adverse effect was observed during the trial; hence, antidote (*Camphora*) was not used.

**Table 1: Baseline information**

Variable	Homoeopathy (n=21)	Placebo (n=12)	P
Age (in years)	22.1±1.2	22.0±1.4	0.83
Gender			
Male	4 (12.1)	5 (15.2)	0.16
Female	17 (51.5)	7 (21.2)	
Weight (in kg)	53.4±9.3	56.7±14.8	0.47
BMI	20.7±2.8	23.2±4.3	0.05
Hb (g/dl)	12.5±1.5	13.3±1.8	0.13
ESR (mm after 1 h)	27.3±13.3	19.0±14.0	0.19
FBS (mg/dl)	85.9±11.3	83.6±10.2	0.02
Total cholesterol (mg/dl)	161.6±17.2	146.4±17.2	0.66
SBP (mm of Hg)	113.0±8.2	112.5±7.5	0.85
DBP (mm of Hg)	76.0±5.6	74.8±5.1	0.55
Blood urea (mg/dl)	20.4±6	21.6±8.2	0.66
SGOT (U/L)	5.1±5.6	5.3±5.8	0.94
SGPT (U/L)	13.1±2.4	11.6±2.8	0.29

SD: Standard deviation; SBP: Systolic blood pressure; DBP: Dystolic blood pressure; Hb: Haemoglobin; FBS: Fasting blood sugar; SGOT: Serum glutamic oxaloacetic transaminase; SGPT: Serum glutamic pyruvic transaminase; ESR: Erythrocyte sedimentation rate

**Table 2: Symptoms produced in 6C potency**

Location	Symptoms observed	Doses	Symptom duration in days
Head	Throbbing pain in right temporal region, <i>agg.</i> bright light, noise; <i>amel.</i> hard pressure, beating head with hand	12	10
	Sudden aching pain in forehead (remained for 2 h only)	12	2
	Mild pain on right side of forehead and in right eye, after half an hour pain spreads to whole head and both eyes followed by stitching pain in parietal region. Pain accompanied by nausea, heaviness in forehead. Pain relieved after bathing next day	9	2
	Piercing pain in forehead, extending to temples and ears. Forehead hot to touch	12	1
	Pain in left occipital region, <i>amel.</i> after sleep	2	3
Nose	Coryza with sneezing, thick yellow nasal discharge, accompanied by nasal blockage, <i>agg.</i> in morning	12	3
Stomach	Appetite increased	1	1
Abdomen	Pain in epigastrium and lower abdomen, <i>agg.</i> traveling; <i>amel.</i> after sleep, drinking water	2	1
Respiratory	Dry cough accompanied by tiredness and increased thirst	12	1
Back	Aching pain in left scapular region, <i>agg.</i> raising arm, stooping	6	1
Extremities	Aching pain in left elbow joint	6	1
Fever	High fever with weakness and body ache	2	1
	Fever with stitching pain in forehead, <i>agg.</i> heat; <i>amel.</i> after sleep, tight bandage	3	1
Generalities	Weakness with body ache more in lower abdomen <i>amel.</i> after sleep	2	2

*agg.*: Aggravation; *amel.*: Amelioration

**Table 3: Symptoms developed by 30C potency**

Location	Symptoms observed	Doses	Symptom duration in days
Head	Sudden aching pain in forehead, <i>agg.</i> noise; <i>amel.</i> tight bandage	12	1
	Pain in forehead with heaviness of head, accompanied with sleepiness, weakness, nausea and pain in eyes; <i>amel.</i> after taking bath	5	1
	Piercing pain on both sides of head, accompanied with pain in eyes, <i>amel.</i> rest	9	1
	Heaviness of head, remained for half an hour, <i>amel.</i> Rest	7	1
	Pain in right side of forehead, accompanied by heaviness of head, <i>agg.</i> at midnight; <i>amel.</i> after sleep	7	1
Face	Nonitching macular eruptions on face. Later eruptions with dryness, <i>agg.</i> evening, washing with warm water. Eruptions subsided, leaving dryness on the area	12	17
Stomach	Nausea, <i>amel.</i> drinking water	12	1
Chest	Painful, red boil in axilla	12	3
Extremities	Stitching pain in right forearm, <i>agg.</i> pressure, lying on affected side; <i>amel.</i> rest	12	4

**Table 4: Comparative investigational values of both the groups**

Variable	Homoeopathy (n=19)		Placebo (n=11)		P
	PME	TME	PME	TME	
BMI	20.7±2.8	20.8±2.9	23.2±4.3	23.3±4.2	0.88
Hb (g/dl)	12.5±1.5	11.9±1.3	13.3±1.8	12.7±1.6	0.91
ESR (mm after 1 h)	27.3±13.3	25.9±20.1	19.0±14.0	11.7±9.5	0.36
FBS (mg/dl)	85.9±11.3	87.5±15.2	83.6±10.2	83.5±12.4	0.75
Total cholesterol (mg/dl)	161.6±17.2	165.6±24.6	146.4±17.2	149.5±16.3	0.89
Blood urea (mg/dl)	19.9±5.8	25.1±4.6	21.3±8.1	23.9±5.7	0.18
SGOT (U/L)	5.1±5.6	16.7±11.7	5.3±5.8	17.5±10.3	0.89
SGPT (U/L)	13.1±2.4	13.4±9.3	11.6±2.8	17.4±12.1	0.88

Statistically significant at  $P < 0.05$ ; Which has been shown after comparing between the groups. BMI: Body mass index; Hb: Haemoglobin; FBS: Fasting blood sugar; SGOT: Serum glutamic oxaloacetic transaminase; SGPT: Serum glutamic pyruvic transaminase; ESR: Erythrocyte sedimentation rate; FBS: Fasting blood sugar; PME: Pretrial medical examination; TME: Terminal medical examination

Among the symptoms manifested in verum group, headache was produced in six provers and in both potencies. Heaviness of head was manifested in only one prover after taking seven doses of 30C potency and this has been also cited in Homoeopathic literature.<sup>[11,12,14]</sup> All other symptoms were produced in single prover each.

The incidence of pathogenetic effects in this study has been found to be 1.09.

### Symptoms Developed During Drug Proving (Control Group)

Each of these symptoms mentioned below were generated and reported by one prover.

#### 1. Mind:

- Difficulty in concentration (4,1)<sup>ψ</sup>

#### 2. Head:

- Headache in single spot left side. Pain was constant, severe, aching with heat of the single spot, *amel.* cold application (6, 1)

- Sudden aching pain in frontal region with burning in eyes, *amel.* pressure (1, 1)
- Aching pain in frontal region with burning in eyes (2, 1)
- Headache with heaviness in frontal and vertex regions, *amel.* closing eyes (12, 3)
- Aching pain in temporal region, *amel.* pressure (9, 3)
- Pulsating pain in right temporal region, *amel.* by pressure (6, 1)
- Pulsating pain in left parietal region, *agg.* talking; *amel.* open air (10, 1)
- Aching pain in occipital region with increased thirst and decreased appetite. Pain *agg.* stooping (10, 1)
- Pain in right occipital region, stretching and pulling sensation, *agg.* stooping, laughing; *amel.* keeping head still, straight (6, 6)
- Heaviness of head, *amel.* bathing (8, 2)
- Stitching pain in right temporal region, *amel.* Sleep, rubbing (4, 1)
- Pain in forehead extends to right frontal region (9, 1)

<sup>ψ</sup>In parenthesis, the first number denotes number of doses after which that particular symptom was produced and the second number denotes the duration (in days) for which the symptom lasted.

- Piercing pain in right side of forehead (8, 1)
  - Aching pain in occipital and parietal region, *agg.* noon, evening; *amel.* tight bandage. Then, aching pain in forehead (5, 2)
  - Dull pain in frontal region of head, *amel.* lying down, pressure (7, 1)
  - Dandruff with itching - white powder falling while scratching head (8, 3).
3. Eye:
- Pain in right eye, *agg.* while reading (8, 1).
4. Ear:
- Pain in right ear (8, 1)
  - Stitching pain in right ear extends to right shoulder (9, 1)
  - Pain in ears (3, 1).
5. Nose:
- Coryza, watery, profuse, bland, nasal discharge with incessant sneezing in bouts of 5–6 sneeze within 2–3 min interval, *agg.* cold water; *amel.* hot drinks and food. It is accompanied with smarting in eyes with watery discharge (12, 3)
  - Running nose (3, 1).
6. Mouth:
- Dryness in the middle of tongue, tongue sticks to upper palate, no relief after drinking water, *agg.* afternoon. It is accompanied with rumbling sensation in abdomen with urge to stool; *amel.* after passing stool (6, 4)
  - Dryness of mouth (8, 2)
  - White coating on tongue (4, 1)
  - Pain in gums on posterior part of lower jaw beyond wisdom tooth followed by redness and inflammation, *agg.* swallowing liquid. Pain extends to neck (9, 6).
7. Teeth:
- Pain in right premolar teeth (4, 1).
8. Face:
- Open comedones on left cheek, *agg.* afternoon (12, 1)
  - Small red eruption on face with slight itching (12, 2)
  - Boil on face (12, 1).
9. Throat:
- Sore throat, *amel.* warm drink. It is accompanied with dry cough, feverish feeling (5, 1)
  - Sore throat, *amel.* warm drink. It is accompanied with cough, coryza, chest pain and heaviness, expectoration yellow, profuse, strain to expectorate the sputum (5, 2)
  - Aching pain in throat. It is accompanied with dry cough and sneezing (5, 5)
  - Pain in throat with tired feeling (3, 2).
10. Stomach:
- Desire to eat chicken but unable to eat at night (6, 1)
  - Loss of appetite (4, 1).
11. Abdomen:
- Aching pain in lower abdomen had to rush to stool with increased gas formation, *amel.* passing stool (6, 1)
  - Cramping pain in abdomen with sudden urge for stool (2, 1)
  - Indigestion with flatulence, rumbling followed by loose, watery stool (2, 1)
  - Stretching pain in lower abdomen (12, 1).
12. Rectum:
- Diarrhea, loose, watery stool, hot. It is accompanied with burning in rectum during stool (prover took momos last night) (4, 2)
  - Diarrhea, yellow, watery, forcefully had to rush to toilet with rumbling and gushing (prover ate chicken in the dinner) (4, 1)
  - Loose stool with rumbling in abdomen reoccurring after passing stool (6, 4).
13. Back:
- Pain in scapular region (9, 1)
  - Aching pain in lumbo-sacral region (11, 2).
14. Extremities:
- Aching pain in right hand near wrist, *agg.* movement; *amel.* pressure. Pain radiates upward and downward (4,2)
  - Aching pain in wrist, *agg.* movement. Pain radiates upward and downward (8, 1)
  - Aching pain in right knee, *amel.* tight bandaging (5, 1)
  - Pustular eruption, redness around pustule slightly painful, tenderness in left leg. Pain radiates to right leg (5, 2)
  - Pustular eruption on right leg (12, 3)
  - Itching in sole of left foot, left knee, which becomes raw and sore (12, 1)
  - Itching in left index finger (12, 1)
  - Small red eruption with slight itching on right leg and right forearm (12, 1)
  - Itching in whole body, *amel.* cold application (1, 1)
  - Itching and small red eruption on leg with yellow urine (2, 4)
  - Small pustular eruption on lateral side of middle finger of right hand (2, 1)
  - Sudden, aching pain in left wrist joint, with sensation as if wrist would break, *agg.* pressure; *amel.* tight bandaging (12, 5)



- Shoulder pain with tired feeling with fever (13, 1)
- Aching pain in left shoulder, *agg.* lifting things; *amel.* lying on left side and pressure (3, 2)
- Peeling of skin of both hands, *agg.* morning (12, 1).

15. Fever:

- Fever (Temp. 103°F) accompanied with coryza, body ache, chill, sweating, and increased frequency of urine. Fever decreased to 100°F after sweating (12, 2).

16. Skin:

- Slight itching all over the body more on scalp, remained the whole day (12, 1).

17. Generalities:

- Weakness with body ache (8, 1).

## DISCUSSION

In the present study, when the symptoms generated in the verum group were compared with the earlier proving symptoms available in the Homoeopathic literature, it was found that symptoms were related to:

### Head

Dyspeptic subjects as per prior proving are similar to headache with nausea and other gastric disturbances in the present study. Similarly, heaviness of head preventing opening the eyes is also found in this study.

### Face

The eruptions in the earlier proving were related to herpes and also having facial neuralgia, but in the present study, no herpes eruptions appeared, rather there are nonitching macular eruptions.

### Stomach and Abdomen

Nausea and increased appetite found in present study are similar to those found in the previous proving. Besides these symptoms, the proving data in older literature has much more in store related to digestive system. There are symptoms related to pain in the epigastrium and hypogastrium in the present study, whereas in the literature, there are colicky symptoms in various parts of the abdomen with flatulence and borborygmi.

### Respiratory System

The nasal symptoms, coryza and nasal blockage, are similar in the present and older literature, but the characteristics of discharges are different, as in older literature, there is dry coryza and epistaxis, whereas in the present study, there is thick yellow

discharge from nose. Symptoms of cough with and without expectoration are found in the literature, but in the present study, dry cough with tiredness and increased thirst have been noted.

### Chest, Back, and Extremities

Symptoms have been generated related to these anatomical regions in the present study and on comparison with older literature, it has been found that:

The symptoms related to eruptions on chest are found in the present study and older literature. However, other symptoms found in the previous proving are not found in the present study.

Under back, the old literature mentions about the symptoms related to the nape of neck, sacrum, coccyx, and even related to the skin, but in the present study, only the symptoms related to pain in the scapular region have been found.

In the extremities section, the present study has symptoms related only to the upper extremities, whereas the older literature has symptoms related to upper and lower extremities involving the joints as well.

### Fever

In the older proving, it has been found that fever has all the three stages of fever, i.e. chill, heat, and sweat; but in the present study, there is no detailing found.

### Generalities

The general weakness and lassitude along with the body ache in different parts of the body are seen in both, in the present and previous provings.

It has been noted that number of symptoms has been produced in both the groups along with a wide range of overlapping of symptoms, but still there were symptoms exclusive of *A. sativum* distinguishing it from the placebo. There is always a scope to improve upon and the parameters for defining the symptoms as characteristic, old and new symptoms may be incorporated. This will be an aid for better qualitative and quantitative analysis of the primary outcome of the study.

In one of the articles, Teut *et al.*<sup>[15]</sup> has mentioned that placebo proving occasionally seem to produce similar symptoms to the proving symptoms, thus casting further doubt on the use of this medium in proving' and has attributed it to nocebo effect. A nocebo response is explained as subject's own

**Table 5: Qualitative symptom profiles of intervention group, control group, and former homoeopathic drug-proving symptoms**

Section	Placebo (C)	<i>Allium sativum</i> 6C (A1)	<i>Allium sativum</i> 30C (A2)	Symptoms produced by intervention ([A1+A2]-C)	Profile of <i>Allium sativum</i> by previous homoeopathic proving <sup>[11-13]</sup>
Mind	Difficulty in concentration				Sadness. Weeping during sleep. Feels he will never get well; cannot bear any medicine; of being poisoned. Sensitive. Impatient impulse to run away. <sup>[14]</sup> Restlessness when alone. Mental anxiety. Moral sensitiveness. Wandering thoughts. <sup>[11]</sup> Weak memory. Lack of ideas. Desire to escape. Cannot bear anything; wants many things and is not pleased with any; every afternoon. <sup>[13]</sup>
Head	Headache in single spot left side. Pain was constant, severe, aching with heat of the single spot, <i>amel.</i> , cold application. Sudden aching pain in frontal region with burning in eyes, <i>amel.</i> , Pressure. Aching pain in frontal region with burning in eyes. Headache with heaviness in frontal and vertex regions, <i>amel.</i> , closing eyes. Aching pain in temporal region, <i>amel.</i> , Pressure. Pulsating pain in right temporal region, <i>amel.</i> , by pressure. Pulsating pain in left parietal region, <i>agg.</i> , talking; <i>amel.</i> , open air. Aching pain in occipital region with increased thirst and decreased appetite. Pain <i>agg.</i> , Stoopng. Pain in right occipital region, stretching and pulling sensation, <i>agg.</i> , stooping, laughing <i>amel.</i> , keeping head still, straight. Heaviness of head, <i>amel.</i> , Bathing. Stitching pain in right temporal region, <i>amel.</i> , Sleep, rubbing. Pain in forehead extends to right frontal region. Piercing pain in right side of forehead. Aching pain in occipital and parietal region, <i>agg.</i> , noon, evening; <i>amel.</i> , tight bandage. Then, aching pain in forehead. Dull pain in frontal region of head, <i>amel.</i> , lying down, pressure. Dandruff with itching - white powder falling while scratching head.	Sudden aching pain in frontal region of head lasting for 2 h only. Heaviness of head lasting for half an hour, <i>amel.</i> , rest Mild headache on right side of forehead and on right eye after half an hour pain in whole head and eyes. Then, stitching type of pain in parietal region. It is accompanied with nausea, heaviness in forehead. The complaints relieved after bathing next day. Piercing pain in forehead extending to temple and ears. Forehead hot to touch. Pain in left occipital region, <i>amel.</i> , after sleep. Throbbing pain in right temple, <i>agg.</i> , bright light, noise; <i>amel.</i> , hard pressure, beating head with hand.	Sudden aching pain in frontal region of head, <i>agg.</i> , noise; <i>amel.</i> , tight bandage Piercing pain in forehead extending to temple and to ears. Forehead hot to touch. Pain in forehead with heaviness of head, <i>amel.</i> , bath. It is accompanied with sleepy, weakness of body, nausea and pain in eyes. Piercing pain on both sides, <i>amel.</i> , rest. It is accompanied with pain in eyes. Pain in right side of frontal region of head, <i>agg.</i> , midnight; <i>amel.</i> , sleep. It is accompanied with heaviness of head. Mild headache on right side of forehead and on right eye after half an hour pain in whole head and eyes Then, stitching type of pain in parietal region. It is accompanied with nausea, heaviness in forehead. The complaints relieved after bathing next day. Throbbing pain in right temple, <i>agg.</i> , bright light, noise; <i>amel.</i> , pressure, hard pressure, beating head with hand. Pain in left occipital region, <i>amel.</i> , sleep.	Sudden aching pain in frontal region of head lasting for 2 h only. Heaviness of head lasting for half an hour, <i>amel.</i> , rest Sudden aching pain in frontal region of head, <i>agg.</i> , noise; <i>amel.</i> , tight bandage Piercing pain in forehead extending to temple and to ears. Forehead hot to touch. Pain in forehead with heaviness of head, <i>amel.</i> , bath. It is accompanied with sleepy, weakness of body, nausea and pain in eyes. Piercing pain on both sides, <i>amel.</i> , rest. It is accompanied with pain in eyes. Pain in right side of frontal region of head, <i>agg.</i> , midnight; <i>amel.</i> , sleep. It is accompanied with heaviness of head. Mild headache on right side of forehead and on right eye after half an hour pain in whole head and eyes Then, stitching type of pain in parietal region. It is accompanied with nausea, heaviness in forehead. The complaints relieved after bathing next day. Throbbing pain in right temple, <i>agg.</i> , bright light, noise; <i>amel.</i> , pressure, hard pressure, beating head with hand. Pain in left occipital region, <i>amel.</i> , sleep.	Heaviness in forehead, almost preventing him from opening his eyes. Headache: With mucous in the throat; in dyspeptic subjects. <sup>[12]</sup> Heaviness in the head, ceasing during menstruation, and returning afterward. Pulsation in temples. Dull pain in occiput in morning, while lying on the back, <sup>[11]</sup> Pressing pains from within outward. Dandruff. Baldness. <sup>[13]</sup>
Eye	Pain in right eye, <i>agg.</i> , reading.				Catarrhal ophthalmia at night; smarting, burning lachrymation; agglutination; returns every night when he tries to read. Tarsi sore with irritation. <sup>[12]</sup> Could read only with spectacles; heaviness in eyes. Profuse watering of eyes without coryza. <sup>[13]</sup>

Contd...

**Table 5: Contd...**

Section	Placebo (C)	<i>Allium sativum</i> 6C (A1)	<i>Allium sativum</i> 30C (A2)	Symptoms produced by intervention ([A1+A2]-C)	Profile of <i>Allium sativum</i> by previous homoeopathic proving <sup>[11-13]</sup>
Ear	Pain in ears. Pain in right ear. Stitching type of pain in right ear extending to right shoulder.	Coryza, watery, profuse, bland, nasal discharge with incessant sneezing in bouts of 5-6 sneeze within 2-3 minutes interval, <i>agg.</i> cold water; <i>amel.</i> hot drinks and food. It is accompanied with smarting in eyes with watery discharges. Running nose.			Catarrhal deafness. Hardened ear-wax and crusts. <sup>[12]</sup> Humming in the ears. <sup>[11]</sup> Deafness of left ear (catarrhal). Customary aural catarrh disappeared; he heard better in diseased ear. <sup>[13]</sup>
Nose		Coryza with sneezing, <i>agg.</i> morning. It is accompanied with nasal blockage with thick yellow nasal discharge.		Coryza with sneezing; <i>agg.</i> morning. It is accompanied with nasal blockage with thick yellow nasal discharge.	Coryza dry rather than fluent, with pressive pain above the root of the nose. On blowing nose, blood from nose at night. <sup>[12]</sup> Increased secretion of nasal mucous with slight blockage of both nostrils. <sup>[11]</sup> Ozaena. smarting at junction of alae nasi and face, mostly left. <sup>[13]</sup>
Face	Open comedones on left cheek, <i>agg.</i> afternoon. Small red eruption with slight itching. Boil on face.		Nonitching macular eruptions on face. Later eruptions with dryness, <i>agg.</i> evening, washing with warm water. Eruptions subsided, leaving dryness on the area.		Lancinations on one side of the face. Dry lips. <sup>[11,12]</sup> Smarting, itching; spots in upper face. Stinging in one side of face. Smarting as from herpetic eruptions near left angle of lips. <sup>[13]</sup>
Mouth	Dryness in middle of tongue, tongue sticks to upper palate, no relief in spite of drinking water; <i>agg.</i> afternoon. It is accompanied with rumbling sensation in abdomen with urging to stool; <i>amel.</i> After passing stool. Dryness of mouth. White coating on tongue. Pain in gums on posterior part of lower jaw beyond wisdom tooth followed by redness and inflammation, <i>agg.</i> swallowing liquid. Pain extending to neck.				Swelling of lower gums. Troublesome feeling during the night and in the morning, as of a hair on her tongue; renewed on waking. <sup>[11,12]</sup> Tongue pale-red with effaced papillae. Dryness of palate. Very copious flow of sweetish saliva into the mouth in the forenoon, after meals; more especially after supper and during the night. Hot taste in mouth, proceeding from throat, strongly reminding him of garlic, immediately after taking the medicine and returning after breakfast to such a degree as to cause a flow of saliva. The symptoms of mouth are <i>agg.</i> by reading. <sup>[12]</sup> Scurvy. Tongue furred white, with a disagreeable taste. Tongue dry at night. Sores in mouth. <sup>[13]</sup>
Teeth	Pain in right premolar teeth.				Tickling sensation in the lower teeth. <sup>[12]</sup> Transient pressive pulling (in the forenoon) in both jaws, and in the right upper molars. <sup>[11]</sup> Toothache paroxysmal and severe. <sup>[13]</sup>

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Table 5: Contd...		Profile of <i>Allium sativum</i> by previous homoeopathic proving <sup>[11-13]</sup>	
Section	Placebo (C)	<i>Allium sativum</i> 6C (A1)	<i>Allium sativum</i> 30C (A2)
Throat	Sore throat, <i>amel.</i> warm drink. It is accompanied with dry cough, feverish feeling. In another prover, it is accompanied with cough, coryza, chest pain and heaviness, expectoration yellow, profuse, strain to expectorate the sputum. Aching pain in throat. It is accompanied with dry cough and sneezing. Pain in throat and tired feeling.		Sensation as of something cold rising in throat. Sensation as of a hot and smarting vapor rising in the throat. Mucous accumulations in the throat, in the morning, with heavy head. Sticky feeling in throat with dryness, tickling, heat, and raw feeling in larynx. <sup>[12]</sup> Inflammation of the throat. <sup>[11]</sup> Anterior part of throat not sensitive to touch. Ulcerated throat. <sup>[13]</sup>
Stomach	Desire to eat chicken but unable to eat at night. Loss of appetite.	Appetite increased.	Voracious appetite. Great hunger from weakness of stomach without appetite. Desire for butter. Thirst; preventing sleep. Burning eructations, after a meal. Eructations exciting copious salivation. Complaints from bad water; from gluttony. Burning in stomach, which is not painful when not touched, but is very sensitive to the least pressure. Lancinations. Weight in stomach which prevents sleep. Pressure inward as from a stone in epigastrium. <sup>[12]</sup> Nausea and loathing of food. Vomiting during the fever. Dull pain in epigastric region, felt only on deep inspiration, but which finally embarrass respiration. <sup>[11]</sup> Belching after every change in diet. Long-standing dyspepsia, especially in old fleshy people, whose bowels are disturbed by slightest deviation from a regular diet. <sup>[12,13]</sup>
Abdomen	Cramping pain in abdomen with sudden urge for stool. Indigestion, flatulence, rumbling followed by loose, watery stool. Aching pain in lower abdomen had to rush for stool with increased gas formation, <i>amel.</i> passing stool. Stretching pain in lower abdomen.	Pain in epigastrium and lower abdomen, <i>agg.</i> travelling; <i>amel.</i> sleep, drinking water.	Wind colic; twisting and pinching around naval. Incomplete (as if interrupted) emission of fetid flatus. Every step on the pavement caused excruciating pain as if the intestines would be torn apart, <i>amel.</i> by lying down. Everything seemed to drag downward. Weight in hypogastrium, immediately after a meal, without urging to stool or urinate. <sup>[12]</sup> Pressure in upper abdomen (stomach and along transverse colon); <i>amel.</i> by sitting bent and pressing with both hands; pain became unendurable on walking out. Borborygmi in the forenoon. Flatulence. <sup>[11]</sup> Pain under short ribs, back, right side. Pain in region of descending colon, just below ribs. Violent burning in abdomen. <sup>[13]</sup>

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Table 5: Contd...	
Section	Placebo (C)
Rectum	Diarrhoea, loose, watery stool, hot. It is accompanied with burning in rectum during stool. (A/f took momos last night). Diarrhea, yellow, watery, forceful with rumbling and gushing had to rush to toilet (A/f ate chicken in dinner). Loose stool with rumbling in abdomen reoccurring after passing stool.
	<b>Allium sativum 6C (A1)</b>
	Dry cough accompanied by tiredness and increased thirst.
	<b>Allium sativum 30C (A2)</b>
	Dry cough accompanied by tiredness and increased thirst.
	<b>Profile of <i>Allium sativum</i> by previous homoeopathic proving<sup>[11-13]</sup></b>
	Expels flatus. Stool first fecal, then watery and hot. Involuntary stools. Diarrhoeic stool, <sup>[11-13]</sup> 3 a.m., preceded, accompanied, and followed by cuttings in abdomen and loins. Normal stool immediately after a meal. Stool delayed from morning until after dinner, great urging, with stool and heat in rectum. Constipation with almost constant dull pain in bowels. Prolapsus ani. Worms. <sup>[12]</sup> Haemorrhoids. <sup>[11,12]</sup> Constipation, which becomes obstinate. <sup>[11]</sup>
	Painful irritation of windpipe when coughing. Scraping in larynx exciting dry cough. Cough seeming to come from stomach. Cough giving rise to perceptible fetid smell. Dry cough after eating. Morning cough, after leaving his bedroom, with extremely copious mucous expectoration. Sudden paroxysms of hard, dry cough while smoking, compelling him to desist. Great difficulty in expectorating a glutinous mucous. Expectoration of thin, yellowish, purulent-looking blood-streaked mucous of putrid odor. Cough, agg. bending head; after eating; by open air. <sup>[12]</sup> Deep-seated cough. Expectoration increased. <sup>[11]</sup>
	Pain in left chest with dark urine. Daring pain in the chest which prevents sleep. <sup>[12]</sup> Oppression of the chest during sleep. Lancinations in one side of the chest. Twitching pain in the side of the chest; it seems to him as if there was an empty spot in his chest. Lancinations under the shoulder blades and pectoral muscles increasing during the cough and deep inspirations, and becoming spasmodic if the latter are renewed several times in succession, with irresistible impulse to cough. Dull stitches in right mamma. Stitches in pectoral muscles and beneath scapulae. Breasts swell after weaning. Swelling of breasts, sensitive to touch. Eruptions of red blotches between the breasts and around the nipples. <sup>[11]</sup> Tension of the pulse and palpitation. <sup>[11,13]</sup>
Cough	Dry cough accompanied by tiredness and increased thirst.
	<b>Allium sativum 6C (A1)</b>
	Dry cough accompanied by tiredness and increased thirst.
	<b>Allium sativum 30C (A2)</b>
	Dry cough accompanied by tiredness and increased thirst.
Chest	Painful, red boil in axilla.

Contd...

**Table 5: Contd...**

Section	Placebo (C)	<i>Allium sativum</i> 6C (A1)	<i>Allium sativum</i> 30C (A2)	Symptoms produced by intervention ([A1+A2]-C)	Profile of <i>Allium sativum</i> by proving <sup>[11-13]</sup>
Back	Aching pain in lumbo-sacral region. Pain in scapular region.	Aching pain in left scapular region, <i>agg.</i> raising arm, stooping.		Aching pain in left scapular region, <i>agg.</i> raising arm, stooping.	Drawing or darting pain in the neck. <sup>[11,13]</sup> Darting pain in the back. <sup>[11,12]</sup> Red spots like ringworm on the back. Itching in the back. Tearing pain in sacrum. Cutting pain in sacrum in the morning. Simple pain in coccyx. <sup>[12]</sup> Insensibility to touch of the anterior portion of the neck. Itching between shoulders. <sup>[11]</sup> Backache. Weak back, child does not learn to walk; marasmus (topically). <sup>[13]</sup>
Extremities	Peeling of skin of both hands, <i>agg.</i> Morning. Itching in left index finger. Itching and small red eruption on leg with yellow urine. Small pustular eruption on lateral part of middle finger of right hand. Pustular eruption, redness around pustule slight painful, tender on left leg. Pain radiating to right leg. Pustular eruption in right leg. Itching in sole of left foot, left knee, which became raw and sore. Small red eruption with slight itching on right leg and right forearm. Shoulder pain and tired feeling with fever. Aching pain in left shoulder, <i>agg.</i> lifting things; <i>amel.</i> lying on left side and pressure. Sudden, aching pain in left wrist joint, with sensation as if wrist would break, <i>agg.</i> pressure; <i>amel.</i> tight bandaging. Aching pain in right hand near wrist, <i>agg.</i> movement; <i>amel.</i> pressure. Pain radiates upward and downward. Aching pain in wrist, <i>agg.</i> movement. Pain radiates upward and downward. Aching pain in right knee, <i>amel.</i> tight bandaging.	Aching pain in left elbow joint.	Stitching pain in right forearm, <i>agg.</i> pressure, lying on affected side; <i>amel.</i> rest.	Aching pain in left elbow joint. Stitching pain in right forearm, <i>agg.</i> pressure, lying on affected side; <i>amel.</i> rest.	Painful feeling of contraction in arm. Pain in forearm; seems as if paralyzed. Some red spots appear on hands. Skin peels off the hands. Tearing pains in fingers extending below the nails. Rheumatism of hip. Tearing pain in hip. Intolerable pain in common tendon of psoas and iliacus muscles; <i>agg.</i> from least movement; trying to cross legs causes him to cry out; but this causes no pain if he lifts the limb gently with his hand; <i>agg.</i> 8 p.m. in bed, cannot then change his position or sleep. Weakness in lower limbs; painful weariness in the thighs. Legs do not grow as rapidly as the rest of the body. Pain as from a sprain in ankle-joint; in toe-joints. Tingling in feet; burning in soles; stiffness in feet. Tearing pain in the feet. Pains <i>agg.</i> by changes of temperature. <sup>[12]</sup> Tension and heat in the right elbow, which is painful during the movement of the arm. Boil on the thigh. All the symptoms are much aggravated by walking. Pains, <i>agg.</i> influence of moist heat. <sup>[11]</sup> Dry heat on back of hands; slight moisture of palms. <sup>[12,13]</sup> Weakness of legs; worse at knees. <sup>[13]</sup>

Contd...

**Table 5: Contd...**

Section	Placebo (C)	<i>Allium sativum</i> 6C (A1)	<i>Allium sativum</i> 30C (A2)	Symptoms produced by intervention ([A1+A2]-C)	Profile of <i>Allium sativum</i> by previous homoeopathic proving <sup>[11-13]</sup>
Fever	Fever (Temperature 103°F) accompanied with coryza, body ache, chill, sweating, and increased frequency of urine. Fever decreased to 100°F after sweating.	High fever with weakness and body ache. Fever with stitching pain in forehead, <i>agg.</i> heat, <i>amel.</i> after sleep, tight bandage.		Fever with increased temperature, weakness and body pain Fever with piercing pain in frontal region, <i>agg.</i> heat; <i>amel.</i> sleep, tight bandage.	Chilliness on one side only. During coldness, redness of face. Vomiting during the fever. Sweat in afternoon. Sweat: acrid; causing itching; fetid. <sup>[12]</sup> Shivering before midday and in evening. <sup>[11,12]</sup> Chilliness from 1 day to another. Catarrhal fever with predominant coldness. General heat during which there is distress. Heat during which she feels twitching in the limbs. Sweat of sour smell. <sup>[11]</sup> Cold at night in bed. Chilliness and heat alternate; more evenings, hard pulse. <sup>[13]</sup> Skin sensitive. Loose; dry; wilted skin. Swelling with itching and burning. Red spots; on hands, on chest, on back. Herpetic itching burning, red or whitish spots on a swollen surface. <sup>[12]</sup> Hard swelling in the integuments. Swelling with the tingling. It blisters the skin (locally). Spots at first white, and which become yellow, and are accompanied with a tingling-itching. Darting-itching. Formication in the skin. Tension in the skin of joints. <sup>[11]</sup> Tetter on ankle. <sup>[13]</sup> General lassitude, especially in the lower limbs to such a degree that he dreads having to go two or three steps upstairs. Morning lassitude which appears to depend on nervous insensibility. Relaxation of the muscles. Sense of oppression; weakness. Drawing in the muscles during the night. Sensation of contraction in the muscles. Tingling in the affected parts. Pain in the glands. Lacerations in the limbs. Often the pains are gradually increased to a high degree and subside in like manner. <sup>[11]</sup>
Skin	Slight itching appeared all over body more on scalp, remained the whole day.				
Generalities	Weakness with body ache.	General weakness. Next day, body ache, more in lower abdomen, <i>amel.</i> sleep.		General weakness. Next day, body ache, more in lower abdomen, <i>amel.</i> sleep.	

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negative expectations and/or negative suggestions from therapists/clinical staff in the absence of any treatment. Nocebo phenomena are generally explained by Pavlovian conditioning and expectations induced by verbal information and suggestions. In this trial also, nocebo phenomenon can be considered and apart from the individual's own perception, this can be attributed to the discussion which usually takes place among the students of homoeopathic colleges who are the participants in the study. This poses a limitation as it is difficult to keep a check on them for not discussing or sharing the experiences. The massive number of symptoms developed in control group could be considered because of such discussions among the students.

Some symptoms of head, skin, nose, extremities, etc., lasted for many days; this shows that drug has affinity toward these regions. Some symptoms appeared immediately after administration of few doses such as increased appetite after administration of 1<sup>st</sup> dose itself whereas symptoms of head, fever, and weakness appeared after administration of 5 doses or more. Skin symptoms which persisted for more than 17 days appeared after the administration of 12<sup>th</sup> dose.

In Boericke's *Materia Medica*,<sup>[14]</sup> *A. sativum* has been mentioned as weight gainer whereas in this proving of *A. sativum*, although BMI has increased, there is no statistically significant difference in the homoeopathic group and also in the control group. Studies have revealed that *A. sativum* can suppress the lipopolysaccharide inflammatory signals by generating an anti-inflammatory gene expression profile and by modifying adipocyte metabolic profile, which is considered in the treatment of obesity.<sup>[16]</sup> In addition, the studies conducted on mice with S – methyl L – cysteine compound extracted from *A. sativum* have shown significant reduction in the animal weight.<sup>[17]</sup>

Apart from BMI, other physiological parameters were also compared. Inter- and intra-group analyses were done and difference in the entry and end point was found, though not statistically significant.

As given in the background of this article regarding garlic in Ayurvedic context that it has action on the digestive system, fattening effects, and it is known to improve appetite, voice, complexion, and found to be useful in diseases of the eye and the heart, low fevers, bronchitis, inflammation, piles, leucoderma, asthma, lumbago, tumors, epileptic fits,

earache. Similarly, in Unani system of medicine, it has diuretic effect and has been found to be useful in inflammation, paralysis, pain in the body and joints, troubles of the sleep, liver, and lungs. It clears the voice, found to be good for lumbago, chronic fevers, thirst, caries of the teeth, leucoderma, and thins the blood.<sup>[4]</sup> In the present study, certain similarities have been found in the symptoms produced and also reported in the older homoeopathic literature. The usefulness of this drug in case of leucoderma, epileptic fits, paralysis, tumors, etc., which is not found in the present study can be explored further.

There are certain other limitations in the study apart from the nocebo effect such as unbalanced randomization allocation, no defined parameters to classify characteristic symptoms, and less number of provers.

## CONCLUSION

The pathogenesis of the *A. sativum* found in this study has produced symptoms which were already noted in the Homoeopathic literature and there are many symptoms which are new. The research scholars such as postgraduate and PhD students, who wish to take up research studies on the drug *A. sativum*, can make this as one of the references and take up further studies. These signs and symptoms need to be subjected to clinical verification study for confirming their therapeutic utility and introducing them in the Homoeopathic *Materia Medica* and can be of help to clinicians.

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## Conflicts of Interest

There are no conflicts of interest.

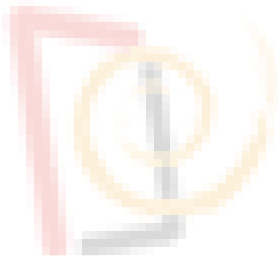
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## एलियम सटाइवम का बहु केंद्रिक, डबल ब्लाइंड यादृच्छिक, होम्योपैथिक विकृतिजन्यता परीक्षण

सार—

**पृष्ठभूमि—** होम्योपैथिक औषध प्रमाणन होम्योपैथिक चिकित्सा प्रणाली का अभिन्न अंग है। यह किसी भी औषधि में व्याप्त विकृतिजन्यता शक्ति का पता लगाने का प्रथम चरण है।

**उद्देश्य—** स्वस्थ मानव परीक्षणदाताओं पर शक्तिकृत एलियम सटाइवम की होम्योपैथिक विकृतिजन्यता प्रतिसाद का विस्तृत अध्ययन करना।

**सामग्री और विधियाँ—** एक बहु केंद्रिक यादृच्छिक, प्लेसिबो नियंत्रित, डबल ब्लाइंड परीक्षण केन्द्रीय होम्योपैथी अनुसंधान परिषद् (सीसीआरएच) के दो केंद्रों पर आयोजित किया गया। पूर्व परीक्षण चिकित्सा जांच के बाद 33 स्वस्थ सिद्धि परीक्षणदाताओं पर यह सत्यता सिद्धि परीक्षण किया गया। परीक्षण के प्रथम चरण के दौरान सभी परीक्षणदाताओं को प्लेसिबो की 12 खुराक 3 दिनों के लिए प्रति दिन 04 खुराकों में विभाजित कर, दी गयी। यादृच्छिकीकरण के बाद, हस्तक्षेप समूह (21 परीक्षणदाताओं) में एलियम सटाइवम की 6सी और 30सी शक्तियों को दो चरणों में प्रमाणित किया। प्लेसिबो समूह में (12 परीक्षणदाताओं) को एक समान तरीके से प्लेसबो दिलाई गई। परीक्षण अवधि के दौरान प्रकट हुए लक्षणों का संकलन परीक्षण दाताओं द्वारा किया गया और फिर परीक्षण प्रमुखों द्वारा उन्हें विस्तारित किया गया। एलियम सटाइवम द्वारा उत्पन्न आँकड़ों को परिषद् मुख्यालय में प्रूविंग-सह-डाटा प्रोसेसिंग सेल में संकलित और विश्लेषित किया गया।

**परिणाम—** 21 परीक्षणदाताओं जो वास्तविक दवा परीक्षण पर थे, में से केवल 9 परीक्षणदाताओं पर लक्षण प्रकट हुए। औषधि (दवा), अधिक या कम रूप से शरीर के लगभग हर अंग में दोनों शक्तियों में लक्षणों को प्रकट करने में सक्षम थी।

**निष्कर्ष:** जो विकृतिजन्यता प्रतिसाद सत्यता प्रमाणिकरण के दौरान हासिल हुआ, उससे एलियम सटाइवम दवा की उपयोगिता के कार्यक्षेत्र में विस्तार होगा और इससे अनुसंधानरत विद्वानों और चिकित्सकों को फायदा होगा। नैदानिक परीक्षण द्वारा इस औषधि द्वारा उत्पन्न लक्षणों का सत्यापन होने पर इस दवा का महत्व और बढ़ जाएगा।

## Ensayo patogénico homeopático, aleatorizado, a doble ciego, multicéntrico de *Allium sativum*

### RESUMEN

**Fundamento:** La patogenesia homeopática es parte integral de la medicina homeopática. Constituye el primer paso para conocer el poder patogénico de un medicamento.

**Objetivos:** Evidenciar la respuesta patogénica a las potencias homeopáticas de *Allium sativum* en personas voluntarias sanas.

**Materiales y métodos:** Se realizó un ensayo aleatorizado, a doble ciego, controlado con placebo, multicéntrico en dos centros del CCRH (*Central Council for Research in Homeopathy*, Consejo Central de Investigación en Homeopatía). Las patogenesias se efectuaron en 33 voluntarios sanos después de un examen médico preensayo. En la primera fase del ensayo, todos los voluntarios recibieron 12 dosis de placebo divididas en 4 dosis al día durante 3 días. Tras la aleatorización, en el grupo de intervención (821 voluntarios), se examinó *Allium sativum* en las potencias de 6C y 30C, en dos fases. En el grupo placebo (12 voluntarios), se administró el placebo de la misma manera. Los examinadores registraron los síntomas manifiestos durante el periodo del ensayo y los directores del ensayo los elaboraron. Los datos generados sobre *Allium sativum* fueron recopilados y analizados en el centro de procesado *proving-cum-data* de la sede principal del CCRH.

**Resultados:** Únicamente 9 de los 21 voluntarios que tomaron el medicamento real manifestaron síntomas. Ambas potencias del medicamento dieron lugar a síntomas, en más o menos todo el organismo.

**Conclusiones:** La respuesta patogénica evidenciada durante la patogenesia amplía el ámbito de indicaciones de *Allium sativum* y beneficiará los becarios y los médicos investigadores. Los síntomas generados por este medicamento tendrán más valor cuando se verifiquen clínicamente.