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Homoeopathic pathogenetic trial of *Blatta orientalis*: A multicentric, double blind, randomised, placebo-controlled trial

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Abstract

Background: The therapeutic effect of *Blatta orientalis* in asthma was found accidentally, but apart from the respiratory symptoms, not much is known about this as a drug through proving in Homoeopathy. Thus, homoeopathic drug proving was carried out, which is the first step in finding pathogenetic effect of the drug substance, for suggestive use in a clinical setting. **Objective:** To elicit the pathogenetic response of *Blatta orientalis* on healthy human provers. **Methods:** A multicentre, randomised, double blind, placebo-controlled trial was conducted at three centres under Central Council for Research in Homoeopathy. The trial was conducted on 47 apparently healthy provers after obtaining their written informed consent. In the first phase, all provers were administered a placebo. In the subsequent two phases, after randomisation, 32 provers in the intervention group were given *Blatta orientalis* in 6C and 30C potencies, and 15 provers in control group were administered unmedicated globules. A maximum of 12 doses were administered in all the phases. The symptoms and signs manifested were noted down by the provers on a structured format, elaborated by the proving masters and the data compilation and analysis were done at proving cum data processing cell. **Results:** The overall incidence of pathogenetic effects is 0.625, and the incidence of pathogenetic effects per prover is 2.75. Pathogenetic symptoms have shown organ affinity for the head, eye, face, abdomen, female genitalia, respiratory system, extremities, back, and skin. **Conclusion:** Further clinical verification study of the pathogenetic response elicited shall expand the therapeutic use of homoeopathically potentised *Blatta orientalis.*

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ORIGINAL ARTICLE

Homoeopathic pathogenetic trial of *Blatta orientalis*: A multicentric, double blind, randomised, placebo-controlled trial

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ABSTRACT

Background: The therapeutic effect of *Blatta orientalis* in asthma was found accidentally, but apart from the respiratory symptoms, not much is known about this as a drug through proving in Homoeopathy. Thus, homoeopathic drug proving was carried out, which is the first step in finding pathogenetic effect of the drug substance, for suggestive use in a clinical setting. **Objective:** To elicit the pathogenetic response of *Blatta orientalis* on healthy human provers. **Methods:** A multicentre, randomised, double blind, placebo-controlled trial was conducted at three centres under Central Council for Research in Homoeopathy. The trial was conducted on 47 apparently healthy provers after obtaining their written informed consent. In the first phase, all provers were administered a placebo. In the subsequent two phases, after randomisation, 32 provers in the intervention group were given *Blatta orientalis* in 6C and 30C potencies, and 15 provers in control group were administered unmedicated globules. A maximum of 12 doses were administered in all the phases. The symptoms and signs manifested were noted down by the provers on a structured format, elaborated by the proving masters and the data compilation and analysis were done at proving cum data processing cell. **Results:** The overall incidence of pathogenetic effects is 0.625, and the incidence of pathogenetic effects per prover is 2.75. Pathogenetic symptoms have shown organ affinity for the head, eye, face, abdomen, female genitalia, respiratory system, extremities, back, and skin. **Conclusion:** Further clinical verification study of the pathogenetic response elicited shall expand the therapeutic use of homoeopathically potentised *Blatta orientalis*.

Keywords: *Blatta orientalis*, Double blind, Drug proving, Homoeopathic pathogenetic trial, Pathogenetic effect

Introduction

Blatta orientalis, commonly known as the Indian cockroach, is a common insect in India. It belongs to the class 'Insecta' and order 'Orthoptera'. It is found abundantly in the dwellings and damp, moist corners in houses. It is deep brown and has a flat body, from an inch to a couple of inches in length. The wings can cover the body completely, and it can fly a short distance. As per Homoeopathic Pharmacopoeia of India (HPI), Ray Hom. Recorder 1890 and a Dictionary of Practical Material Medica, Clarke has been mentioned as the authority for *Blatta orientalis*.[1]

Ray Hom. Recorder discusses an incident that led to the discovery of this drug's therapeutic use.[2]

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Many years ago, an elderly man suffered from severe asthma. After trying both conventional and alternative treatments without relief, one day, after his usual cup of afternoon tea, his chest tightness was alleviated, and the asthma attack ceased. Upon examining the teapot, the source of the cure was found - the dead cockroach. His friend decided to test the curative power of the cockroach in asthma and used a mother tincture prepared in alcohol. He then started giving a few drops daily to asthmatic patients willing to try it. The results were so promising that patients began coming from across the country. Since then, *Blatta orientalis (B. orientalis)* has become a homoeopathic remedy. It has proven to be a wonderful treatment for chronic asthma, characterised by suffocation from excessive mucus, coughing, and shortness of breath.

B. orientalis haemolymph had shown in vitro antibacterial activity against five bacterial strains, namely, Staphylococcus aureus, Proteus mirabilis, Salmonella typhi, Pseudomonas aeruginosa, and Escherichia coli. This indicates haemolymph of *B. orientalis* may have the potential antimicrobial activity.[3] Also, ethanol extracts of the cockroach's guts and exoskeletons investigated had shown some level of activity against the selected bacterial pathogens, including methicillin-resistant Staphylococcus aureus (MRSA).[4]

Significant reduction in mesenteric mast cell degranulation, serum IgE level, and eosinophil cell count was observed in the *B. orientalis* mother tincture (Q) treated rat group when compared with the sensitised control rat group. It reveals that the broad activity of *B. orientalis Q.* may have nonselective anti-asthmatic activity. The anti-anaphylactic activity of *B. orientalis Q* may be due to mast cell stabilisation, suppression of IgE, and eosinophil cell count.[5]

An earlier study studied the intranasal application of *B. orientalis Q* as part of a nasal gel designed to control milk aspiration-induced eosinophilia, concluded that there was a "decreased eosinophil cell count as compared with toxicant" as well as the absence of any histopathological damage.[6]

The mother tincture of *B. orientalis* is prepared after crushing and triturating the whole insect by the old method, as per class IX of Pharmacopoeia.[7] It is a remedy for asthma, especially associated with bronchitis.[8] It acts best in stout and corpulent patients. There is much pus-like mucous; suffocation is threatened by the accumulation of mucous in the bronchi.[9] Oppression of the chest as if a weight or heaviness is there on the chest.[10] It is useful in cases of bronchitis and tuberculosis, where there is much shortness of breath, along with a cough.[11]

Details regarding its effect on respiratory complaints were well described in the literature. However, there is a definite need for detailed systemic drug proving to explore and find the pathogenetic effects of this drug in healthy human volunteers, so that further research studies can be taken up to ascertain the therapeutic utility of this drug of great value. Hence, the expert body of the Central Council for Research in Homoeopathy recommended taking up a proving trial of this drug as per the approved protocol.

Materials and methods

Trial design

This was a multicentric, prospective, parallel-arm, randomised, double-blind, placebo-controlled study with allocation of verum: placebo: 70:30.

The trial was registered in CTRI retrospectively (2017/11/010678).

Participants

Eligibility criteria

Inclusion criteria

Individuals of both sexes in the age group 18 to 60 years, certified as apparently healthy by the medical experts, found intelligent enough to record carefully the symptoms generated during drug proving and not having taken any medication in the last two months, were eligible.

Exclusion criteria

Volunteers suffering from any acute or chronic disease (like the renal, endocrine, pulmonary, central nervous system, cardiovascular, immunological, dermatological, gastro-intestinal or any other body system), colour blindness, anxiety or hysteria, having any addictions, undergoing any kind of medical treatment, undergone surgery in last two months, smokers who smoke more than 10 cigarettes /day, women during pregnancy/ puerperium/lactating and participated in another clinical or proving trial during the last six months were excluded.

Screening and enrolment

The volunteers who expressed their interest in participating in the trial and submitted the written informed consent form underwent basic screening to understand their health status, followed by a pre-trial medical examination (PME) wherein the baseline characteristics and the findings for systemic examination by the consultants of the conventional system of medicine were documented. Laboratory investigations such as complete blood count (CBC), blood sugar fasting, lipid profile, liver function test,

kidney function test, urine [routine and microscopy], stool [routine and microscopy], electrocardiogram, chest X-ray (PA view), and USG of the whole abdomen were done. After screening at different centres, 47 volunteers were enrolled as provers. This was followed by randomisation into two groups, i.e. verum (32) and control (15).

Study setting

The study was conducted at three drug-providing centres in India: Dr. D. P. Rastogi Central Research Institute (H), Noida, Uttar Pradesh; Drug Proving Unit, Bhubaneshwar, Odisha and Regional Research Institute, Gudivada, Andhra Pradesh, India.

Duration of study

The study was conducted at three centres from July 2014 to March 2015. The total duration of the study was nine months.

Intervention

Verum group

B. orientalis in 6C and 30C potencies in 100 ml sealed bottles was procured from a GMP-certified Homoeopathic drug manufacturer (Willmar Schwabe India Pvt Ltd, Noida) (Batch number 869) in India. Globules of number 30 were medicated with these potencies at the nodal office of drug proving.

Control group

Placebo was prepared using unmedicated globules (number 30) moistened with unmedicated dispensing alcohol and was therefore indistinguishable from the homoeopathic drug.

Sample size

A total of 75 participants were screened, and 47 apparently healthy volunteers comprising 13 males and 34 females were enrolled after screening, detailed case taking, followed by investigations and physical examination by the consultants of modern medicine. Most of the participants were students from homoeopathic medical colleges. As this was considered a Phase I clinical trial,[12] where in 15-20 healthy volunteers were enrolled, thus in drug proving protocol at each centre minimum 15 and maximum 20 volunteers were enrolled. Further, the protocol which had been followed for conducting the drug proving trials is in consonance with the Guidelines published by international organisations like ECH and LMHI.[13] These guidelines also refer to Drug Proving trials under Phase I clinical trials.

Randomisation

Randomisation was done online using randomizer.org[14] at the nodal center for drug proving and provers were categorised into two groups: verum (n = 32) and control (n = 15). A simple randomisation method was used to randomise the provers at each center.

Each prover was assigned a unique ID (UID) as the prover code and the random numbers generated during randomisation were considered for allocating the provers under the two groups. Being a double-blind study, these code numbers for the provers along with the information about the group allocation, were kept under lock and key at the data-processing cell at the nodal office of drug proving. The decoding of the group allocation was done after the compilation of the symptoms produced in both groups.

The investigational proving substances (IPS), i.e. homoeopathic drug and placebo, were dispensed in identical form, visually indistinguishable from each other, in glass vials labelled with the prover's code or UID. Provers (participants) and the Proving Master (investigator) were kept blinded to the group allocation and to the identity of the drug. The IPS in different potencies were supplied in separate glass vials bearing the code numbers of the respective prover and the quota number.

The vials with UID for each prover were received by the proving masters at respective centers and given to the provers in a phased manner.

Proving procedure and data recording

At each study center, a proving master supervised the provers 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 examinations and laboratory investigations were filled in the prescribed proforma. All 47 provers selected from three centers were subjected to three phases of proving.

- ***Phase I***: This was the placebo phase. It was useful in generating the prover's response to the placebo and, therefore, symptoms generated by the prover in this stage act as a control for subsequent phases (intra-prover and inter-prover response).
- ***Phase II and III***: In these phases, the IPS in 6C and 30C potencies were administered in ascending order in the verum group. However, identical non-medicated globules were administered in the control group in all these phases of the trial.

In each phase, 12 doses (one dose comprising of four globules of size number 30) of coded drug or placebo as per randomisation were administered, divided into 4 doses/day for three days (if no symptom/

sign arises) and provers were asked to stop taking further doses as soon as any symptom(s)/ sign(s) appeared. At least two doses were administered every day to the provers during college hours. While the rest of the doses were provided to them in vials.

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 and in the subsequent washout 30 days in 'Prover's Day Book Proforma' before starting the next phases following the same dose schedule. The entries made by the provers were verified by the proving master, and each symptom was completed in respect to their location(s), sensation(s), modalities, concomitants, extension of symptoms, causation, clinicopathological findings and other treatment taken, if any, in 'Symptoms Elaboration Proforma'. If any sign(s)/symptoms(s) appeared, 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 was noted.

If no sign(s)/symptoms(s) appeared after consuming all 12 doses of the IPS, the provers were further asked to note down any change for the subsequent 30 days. If no sign(s)/ symptoms(s) appeared during these 30 days, the prover was administered the doses of the next potency of the IPS.

After completion of the trial in three phases, the provers underwent post-trial or terminal medical examination (TME). The compilation of data recorded in 'Prover's Day Book Proforma', 'Symptoms Elaboration Proforma', 'Pathological Report Sheets', and comparison between 'PME and TME sheets' was done at the drug proving-cum-data processing cell. After decoding the groups, the sign(s) and/or symptom(s) generated by the provers in both groups were analysed to find the pathogenetic symptoms of the drug.

Blinding and allocation concealment

Unblinding or breaking of the randomisation codes was done at the nodal office after the study was completed at all the study sites.

Statistical methods

The data analysis of the demographic data and laboratory investigations, using an independent t-test for the continuous variables and a chi-square test for the categorical variables, was done for both the groups at baseline and the end of the trial with Statistical Package for Social Sciences version 20 for Windows (IBM). Reporting is adhered to the Consolidated Standards of Reporting Trials (CONSORT)[15] and Reporting data on homeopathic treatments (RedHot), a supplement to CONSORT.[16]

After decoding, the sign(s) and/or symptom(s) produced by the provers of the verum group were separated from those produced by the provers in the control group. Further "descriptive analysis" was performed to assess the pathogenetic effect (signs and/or symptoms) developed in the provers during the trial. To distinguish between the placebo effect and the nocebo effect caused by proving symptoms, intra- and inter-prover analyses were conducted in both groups. The intra-prover analysis compared the symptom(s) and/or sign(s) produced by each prover in the first phase with those reported in subsequent phases. Additionally, an inter-prover analysis at each center identified symptom(s) and/or sign(s) common to both groups. The symptoms were classified as recent symptom (RS), new symptom (NS), old symptom (OS), alteration in present or old symptom (AS), and unusual symptom (US).

Ethics and consent

The Institutional Ethics Committee of the Central Council for Research in Homoeopathy approved the study protocol vide letter no. 1-3/2014-15/CCRH/Tech./18th EC dated 14th July 2014, and the drug for conducting the trial. Proving Masters with a minimum of five years of experience in homoeopathic practice were sensitised to the drug proving research protocol of the Central Council for Research in Homoeopathy. An orientation lecture for the students and staff of the colleges was organised, and participants who volunteered to take part in this trial were provided details in the form of a 'Participant Information Sheet', the procedure of the trial, and then the 'written informed consent form' was obtained from all the volunteers before enrolment in the study. The trial was conducted following the International Conference on Harmonisation Guidelines for Good Clinical Practice, Helsinki Declaration.[17]

Results

From three centers, 47 apparently healthy volunteers were enrolled as provers. Of 47 provers, 32 were in verum and 15 were in control groups. Out of 32 provers who were kept on verum, 23 provers produced symptoms. A total of 156 symptoms were reported by provers in both groups (Table 1). Of 156 symptoms, 104 symptoms developed in the verum group (including 53 symptoms produced in the placebo phase and 51 symptoms developed with the 6C and 30C potencies), and 52 symptoms were reported in the control group. The flowchart shows the number of volunteers screened, enrolled, and randomised in two groups, and the number of

Table 1. Number of symptoms developed during drug proving

Centre	Group	Potency*			Total	Incidence of pathogenetic effects
		Placebo	6C/Placebo	30C/Placebo		
CRI (H), Noida	VERUM	36	15	14	**65**	**0.7**
	CONTROL	20	8	5	**33**	
DPU, Bhubaneshwar	VERUM	15	6	10	**31**	**0.63**
	CONTROL	8	6	4	**18**	
RRI, Gudivada	VERUM	2	6	0	**8**	**0.54**
	CONTROL	0	1	0	**1**	
TOTAL		**81**	**42**	**33**	**156**	

***Potency:** Placebo was administered throughout in all phases in the control group, in comparison to different potencies in the verum group. Pathogenetic symptoms observed are highlighted in red colour; in total 51 pathogenetic symptoms were observed.

provers who developed symptoms during the trial Fig. 1. The average age of the verum group was 21.64 ± 3.11 years and that of the control group was 21.58 ± 3.09 years. The baseline information in both groups was comparable ($p \geq 0.05$) and well-matched, as shown in Table 2.

Pathogenetic effect of Blatta orientalis

Quantitative analysis

Table 1 depicts a total of 156 symptoms that were produced in this trial, which included 105 placebo symptoms and 51 pathogenetic symptoms. In the verum group, 3 provers reported symptoms only in the placebo phase. Whereas, 20 provers in the verum group developed 51 pathogenetic symptoms (31 symptoms, 14 symptoms and 6 symptoms reported from DDPR CRI (H), Noida; DPU, Bhubaneswar and RRI (H), Gudivada respectively). Apart from these 51 symptoms, 4 additional symptoms were reported as changes in physical generals from PME to TME in the verum group. Thus, there are 55 pathogenetic symptoms developed in the Verum group. Out of these 55 pathogenetic symptoms, 27 symptoms were produced in 6C potency, 24 in 30C potency, and 04 symptoms reported as changes in the physical generals were due to the overall effect of the drug. In the control group, 9 of the 15 provers reported 52 symptoms.

The overall incidence of pathogenetic effects in this trial is calculated by dividing the number of provers (20) who reported at least one pathogenetic effect by the total number of provers (32) who had taken the medicine (IPS).[18] Thus, the incidence of pathogenetic effects in this trial is 0.625. The overall incidence of pathogenetic effects at the study sites, namely CRI (H), Noida was 0.7; DPU, Bhubaneshwar was 0.63 and RRI (H), Gudivada was 0.54. (Table 1)

The incidence of pathogenetic effects per prover is calculated as the total number of findings observed in the trial within the verum group, divided by the total number of provers who reported those symptoms. In this trial, 51 symptoms were reported during the trial and 4 symptoms were reported as changes in physical general from PME to TME in the verum group by 20 provers. Hence, the incidence of pathogenetic effects per prover in this trial is 2.75.

The duration of the symptoms ranged from 10 minutes to 17 days.

Table 2. Baseline information

Variable	Verum ($n = 32$)	Placebo ($n = 15$)	*p-value*
Age	21.64 ± 3.11	21.58 ± 3.09	0.95
Gender			
Male	9	4	0.917
Female	23	11	
BMI	22.83 ± 3.94	22.56 ± 3.94	0.82
Hb	11.81 ± 1.24	11.78 ± 1.262	0.93
TLC	6726.21 ± 1860.21	6726.78 ± 1901.09	0.99
ESR	11.1 ± 7.33	11.2 ± 7.44	0.96
FBS	79.83 ± 13.42	79.78 ± 13.71	0.99
Total cholesterol	170.3 ± 24.9	170 ± 25.37	0.96
Urea	25.85 ± 8.28	25.80 ± 8.46	0.98
Alkaline Phosphate	139.49 ± 28.71	139.8 ± 29.26	0.97
SGOT	18.57 ± 7.58	18.52 ± 7.74	0.98
SGPT	19.36 ± 7.25	19.15 ± 7.27	0.92

Abbreviation: SD: Standard deviation; BMI: Body mass index; Hb: Haemoglobin; TLC: Total lymphocyte count; ESR: Erythrocyte sedimentation rate; FBS: Fasting blood sugar; SGOT: Serum glutamate oxaloacetate transaminase; SGPT: Serum glutamate pyruvate transaminase.

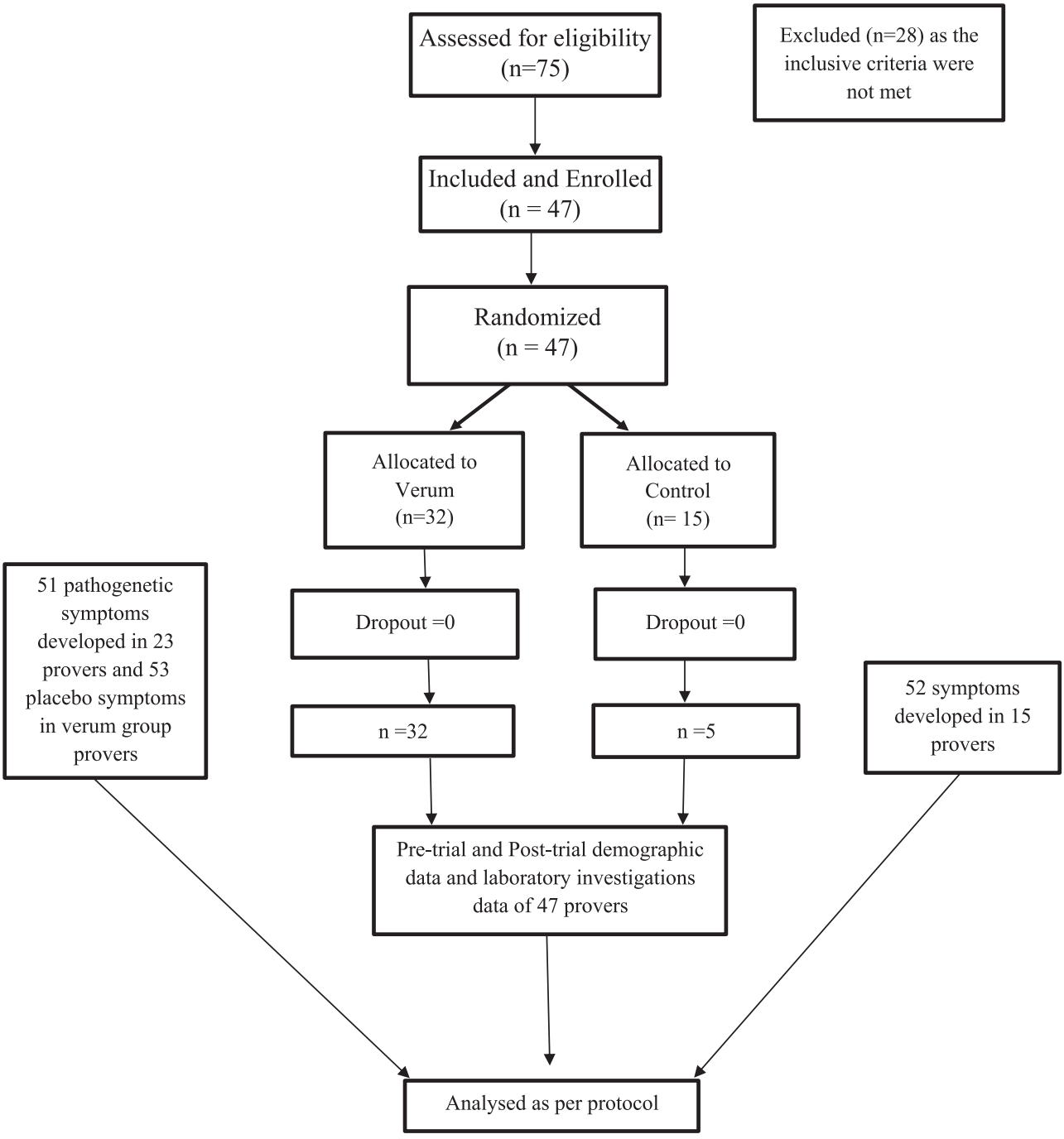

Fig. 1. Flow chart of study participants

The drug has shown an affinity toward the organ/system - head, eye, nose, face, throat, abdomen, female genitalia, respiration and cough, extremities, back, and skin. No symptoms related to vision, ear, teeth, male genitalia, urinary system, and sleep were reported.

Another aspect that has been noted is that the drug has a right-sided affinity, which was reflected in symptoms related to the head, eye, extremities, and skin.

Qualitative analysis

The final pathogenesis of the drug evolved is cited in Table 3.

Symptoms appearing in two or more provers, at two different study sites, and a prover developing the same symptom after administration of the different potencies indicate the probability that they belong to the drug pathogenesis, which is presented in Table 4.

Table 3. Final pathogenesis of *Blatta orientalis* evolved after the trial

Location	Symptoms
Mind	Cheerful and pleasing (change in disposition from PME to TME)
Head	Dull aching pain in whole head; amel. sleeping from 5 pm to 9 pm. (1,6C)[#] (12, 4hrs)[$]
	Aching pain in the whole head with the heaviness of eyes; agg. night. (10 pm to 12:30 am). (1,30C)[#] (3, 2.5hrs)[$]
	Pain in the head with sensation as if the brain is loose inside. This is accompanied by nausea, vomiting, and pressing pain in orbits; agg. open air, bright light. (1, 30C)[#] (3, 1 day)[$]
	Dull aching pain in the whole head with disturbed sleep; agg. night, amel. after sleep. The next day shifting dull aching pain at the vertex, frontal, and parietal region; agg. when idle, amel. pressure, when occupied, laughing, after eating and drinking, after eructation, after menstrual flow, and disappeared at 7 pm. (1, 30C)[#] (12, 2 days)[$]
	Aching and bursting pain in the frontal region; agg. morning increasing till afternoon then decreased gradually. (1, 6C)[#] (6, 4 days)[$]
	Aching pain in the frontal region of the head; agg. sunlight, amel. open air. (1, 6C)[#] (12, 1 day)[$]
	Aching pain with heaviness in the frontal region of the head. (1, 30C)[#] (8, 3 days)[$]
	Aching pain in the frontal region of the head during the day; agg. Cold (1, 30C)[#] (12, 1 day)[$]
	Throbbing pain in the frontal region of the head associated with nausea; agg. evening, amel. rest. (1, 6C)[#] (11, 1hr)[$]
	Aching pain in the frontal region of the head associated with nausea and thirstlessness; agg. morning, during the day. (1, 6C)[#] (4, 1 day)[$]
	Aching pain in the frontal region of the head; agg. evening. (1, 6C)[#] (4, 3 days)[$]
	Throbbing pain in the frontal region of the head; agg. morning, daytime. (1, 30C)[#] (8, 2 days)[$]
	Bursting pain in the forehead with weakness and irritability; agg. rising from sitting posture, amel. walking, dim light. (1, 6C)[#] (8, 2 days)[$]
	Pulsating pain in forehead and temples as if it would burst; agg. exertion, amel. lying down, pressure. (1, 30C)[#] (12, 5 days)[$]
	Drawing pain in the right temporal region at 3 p.m. (1, 6C)[#] (2, 10 minutes)[$]
	Continuous throbbing pain in the right temporal and periorbital region; agg. evening. It is associated with restlessness, disturbed sleep, and diminished appetite. (1, 6C)[#] (3, 3 days)[$]
	Heaviness in the occipital region; agg. noise, talking, laughing, amel. rest, sleep. This is associated with thick green nasal discharge in the afternoon followed by a feverish feeling with drowsiness throughout the day and nasal obstruction at night. Headache relieved but nasal discharge continued for 5 more days. (1, 30C)[#] (9, 13 days)[$]
Vertigo	Vertigo; agg. standing, amel. lying. B.P-98/70 mmHg (6 pm to 9:30 pm). (1, 6C)[#] (7, 3.5hrs)[$]
	Vertigo in the evening for 1 hour; agg. standing, walking, amel. lying. B.P-122/78 mmHg. (1, 30C)[#] (1, 2 days)[$]
Eye	Watering of eyes with redness; amel. washing with cold water. (1, 6C)[#] (8, 2 days)[$]
	Profuse watering and itching of eyes (6:30 pm to 7:30 pm). (1, 30C)[#] (3, 1hr)[$]
Nose	Sneezing with watery discharge occurred for 2 days (O.S). Later nasal blockage for 4 days and subsequently blood streaked thick yellow discharge. The symptoms persisted for 15 days. (1, 6C)[#] (8,17 days)[$]
	Watery discharge from nose; agg. cold, amel. warm. (1, 6C)[#] (12, 1 day)[$]
	Blockage of both nostrils with thick white discharge. (1, 30C)[#] (12, 1 day)[$]
Face	Large, red, painful acne on forehead and cheek associated with increased thirst. (1,6C)[#] (8, 8 days)[$]
	Acne on the right side of the face and right side of the upper back with slight itching. (1, 6C)[#] (12, 3 days)[$]
	Stitching pain in the submandibular region; agg. turning the head. (1, 30C)[#] (5, 1 day)[$]
	Painful acne on the face, forehead, and right cheek. (1, 30C)[#] (4, 5 days)[$]
Throat	Soreness in the throat with difficulty in swallowing, especially cold food, has to hawk continuously; amel. warm fluids. (1, 30C)[#] (4, 2 days)[$]
Stomach	Appetite increased. (change from PME to TME)
	Appetite - easy satiety. (change from PME to TME)
Abdomen	Continuous dull aching pain in the right renal angle. (1, 6C)[#] (12, 5 days)[$]
	Crushing pain in both inguinal regions; agg. walking, standing, amel. rest. (1, 6C)[#] (12,1 day)[$]
Rectum	Constipation (hard stool) at 7 am. (1, 6C)[#] (12, 4 days)[$]
	Burning in anus while and after passing hard stool in the morning; agg. standing, amel. sitting. (1, 6C)[#] (8, 5 days)[$]
	Watery, offensive stools (5-6 times) with pain in the abdomen. (1, 6C)[#] (12, 1 day)[$]
Female genitalia	Reddish, tender eruptions on the pubic region. (1, 6C)[#] (8, 4 days)[$]
	Thick, brownish, red mucus discharge instead of normal menstrual flow for 3 hours in the morning followed by normal flow. (1, 30C)[#] (12, 1 day)[$]
	Profuse, acrid, watery leucorrhoea causing burning and itching of parts touched; agg. walking, afternoon (2 pm to 6 pm), amel. warm application. (1, 30C)[#] (4, 5 days)[$]
Cough	Cough with expectoration; agg. early morning, sleep, amel. sitting, drinking water. The symptoms persisted for 3 days and reappeared after 5 days and continued for 4 days. (1, 6C)[#] (8, 7 days)[$]
	Spasmodic dry cough associated with irritation in throat, tenderness at left supra-orbital region; agg. morning, night, lying down, amel. drinking warm water. (1, 30C)[#] (9, 14 days)[$]
	Dry cough. (1, 30C)[#] (12, 2 days)[$]
	Dry cough with obstruction of the nose, increased thirst; agg. morning (O/E- Mild enlargement of both tonsils). (1, 30C)[#] (7, 3 days)[$]

(Continued)

Table 3. Continued

Location	Symptoms
Back	Papular eruptions with itching on the back (more on the right side). (1, 6C)[#] (6, 6 days)[$]
	Aching pain in the lower back; agg. sitting, bending, amel. rest. (1, 6C)[#] (12,1 day)[$]
	Aching with stiffness and restricted movement in the right side of back; agg. motion. (1, 30C)[#] (8, 4 days)[$]
Extremities	Numbness in the right leg; agg. evening. (1, 6C)[#] (12, 1 day)[$]
	Aching pain in knee joints extending to calf muscles; agg. night, amel. massage. (1, 30C)[#] (8, 2 days)[$]
	Aching pain in calf muscles; agg. motion, amel. pressure. (1, 30C)[#] (9, 3 days)[$]
	Aching pain in lower extremities; amel. lying. (1, 30C)[#] (1,1 day)[$]
Skin	Small vesicular eruption on chin and forehead with oozing of scanty, white discharge; agg. on scratching. (1, 6C)[#] (8, 9 days)[$]
Generalities	Lethargy; agg. noon till night. (1, 6C)[#] (4, 2 hrs.)[$]
	General weakness. (1, 6C)[#] (12,1 day)[$]
	Frequent gastrointestinal complaints. (change from PME to TME)
	Aversion to noise and crowd. (change from PME to TME)

[#] In the first parenthesis, the 1st number given after every symptom denotes the number of provers who developed that symptom, and the 2nd number denotes the potency.

[$] In the second parenthesis, the 1st number denotes the number of doses of the drug after which that symptom has developed, and the 2nd number is the duration for which the symptom lasted.

Agg. – Aggravation; Amel. – Amelioration; O.S. – Old symptom.

Table 4. Probable pathogenesis of *Blatta orientalis* evolved after the trial

Location	Symptom	Number of provers	Number of centres
Headache	Location: temporal Characteristic: throbbing pain	3	3
Headache	Location: Frontal Characteristic: aching/throbbing Modality: aggravation in morning	2	2
Face	Painful acne on forehead and cheeks	3	2
Cough	Aggravated in morning with increased thirst and amelioration on drinking water	3	3
Extremities	Aching pain in legs	2	2

Table 5. Analysis of laboratory parameters at TME for provers of both groups

Laboratory parameters	Verum group (n = 32)	Control group (n = 15)	*p*-value
BMI	22.71 ± 3.91	22.53 ± 3.61	0.88
Hb	11.85 ± 1.94	11.84 ± 1.93	0.98
TLC	7101.2 ± 1317.8	7012.4 ± 1315.8	0.83
ESR	12.04 ± 7.42	11.87 ± 7.45	0.94
FBS	88.24 ± 11.32	89.00 ± 11.05	0.82
Total cholesterol	157.88 ± 26.79	157.02 ± 26.80	0.91
Urea	26.97 ± 7.85	26.90 ± 7.90	0.97
Alkaline Phosphate	132.32 ± 34.90	131.84 ± 34.44	0.96
SGOT	24.03 ± 6.72	23.65 ± 6.80	0.85
SGPT	24.77 ± 6.30	24.21 ± 6.72	0.78

Statistical analysis was performed using the paired t-test, for various laboratory parameters of provers in both groups (verum and control) at TME (Table 5). Changes in laboratory parameters at TME in both groups were not statistically significant. No severe symptom/adverse event was reported.

Discussion

The available homoeopathic literature[2,8–11] mentions the effect of this drug mainly on respiratory issues. The trial has not only confirmed the known traditional therapeutic use of this drug in respiratory complaints, but has also discovered a broader outline of therapeutic indications for this drug. Thus, this trial can be considered the first systematic scientific study in the homoeopathic system of medicine to understand the extensive pathogenetic effects of *Blatta orientalis*.

As this study has confirmed the symptoms reported in the existing homoeopathic literature and being a multicentric study, similar symptoms have been

reported by provers at different time points in different geographical locations, thus confirming the therapeutic utility of this drug for patients suffering from such symptoms.

This pathogenetic trial has shown overlapping of a few aspects of a symptom, like location, sensation, or modalities, in both verum and control groups that can be attributed to being 'nocebo effect'. The term nocebo (Latin *nocēbō*, "I shall harm") was coined by Walter Kennedy in 1961 to denote the counterpart of placebo (Latin *placēbō,* "I shall please"). By definition, a nocebo effect is the induction of a symptom perceived as negative by treatment. A nocebo response is a negative symptom induced by the patient's negative expectations.[19] Nocebo responses are also frequently observed as adverse events in the placebo arm of randomised controlled drug trials and are known to be a confounding factor in clinical drug trials.[20] Thus, this trial being a double-blind study, the provers in the control group responded to the administration of a placebo with such a negative expectation, and similarly, is the case with the provers in the verum group who had developed symptoms in 1st phase of the trial in which a placebo was administered to them.

The nocebo response, as background noise, would strongly disturb any HPT and would make it extremely difficult to identify specific symptoms. However, in this trial, a qualitative analysis approach to identify homoeopathic characteristic symptoms has been used to filter out such background noises.

Though symptoms of upper respiratory tract infection were present in both groups, the characteristics were different, especially the nasal discharges. Further symptoms like irritation in the throat, watering and redness of eyes reported in this trial and knowing the effect of the drug on the mast cells and IgE levels,[5] these symptoms should be considered for further clinical trials and the IgE levels of such patients may also be evaluated after the trial to validate the effect of this drug.

Painful acne, vesicular eruptions with white discharge, acrid leucorrhoea, and productive cough are similar to symptoms caused by a bacterial infection in the body. This may confirm the potential antibacterial effect of *B. orientalis*[4] and open an avenue of its use in bacterial infection after clinical verification.

Further, susceptibility is the inherent capacity of the individual to react to external stimuli.[21] The changes in the physical generals, tendencies, and disposition noted in this trial clearly show how the susceptibility of a prover gets affected by the drug. These findings further demonstrate the pathogenetic and therapeutic effects on a prover. The components like improvement in appetite and change in disposition from melancholic to cheerful confirm that the drug proving does help in correcting the susceptibility and improving the health status of the participants.

Apart from these, the intensity of symptoms did not cause any hindrance in the day-to-day activities of the prover. Thus, this is in corroboration with the teachings related to drug proving that the artificial disease developed by any medicinal substance is transient and does not cause pathological changes in a healthy volunteer.[22]

The limitation of the study was that only the college students participated in the trial, whereas the desired age group was 18–60 years. Further, the provers of non-homoeopathic background were also not available for participating in this trial. The relevant laboratory investigations could not be done for each prover who has reported any symptoms to corroborate between the subjectivity and objectivity of those symptoms. There are chances that confounding factors like climate change, stressful conditions, etc., which could have resulted in some of the symptoms, are not reported appropriately. However, efforts have been made to minimise such factors by carrying out the quantitative and qualitative analyses.

Conclusion

This trial has not only brought forth the pathogenetic effects of this drug but has also thrown light on its therapeutic effect. All these effects are enough clues to further explore the utility of this drug in their respective spheres. Thus, considering the overall profile of the drug, consisting of the subjective as well as the objective findings, the outcome of this trial must undergo clinical verification and more validation studies in a clinical setting. The confirmation of the proving data, along with its conformation with the laboratory investigations such as absolute eosinophil count and IgE level, will enrich the materia medica and further enhance the clinical utility of this drug by the profession.

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Conflict of interest

None declared.

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Data Availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Essai pathogénique homéopathique de *Blatta orientalis* : essai multicentrique, en double aveugle, randomisé et contrôlé par placebo

Contexte : L'effet thérapeutique de *Blatta orientalis* sur l'asthme a été découvert fortuitement, mais hormis les symptômes respiratoires, les connaissances sur ce médicament en homéopathie sont limitées. Français Ainsi, la validation homéopathique du médicament a été réalisée, ce qui constitue la première étape incluant l'effet pathogénique de la substance médicamenteuse, pour une utilisation suggestive dans un contexte clinique. **Objectif** : Susciter la réponse pathogénique de *Blatta orientalis* sur des expérimentateurs humains en bonne santé. **Méthodes** : Un essai multicentrique, randomisé, en double aveugle, contrôlé par placebo a été mené dans trois centres sous l'égide du Conseil central de recherche en homéopathie. L'essai a été mené sur 47 expérimentateurs apparemment en bonne santé après avoir obtenu leur consentement éclairé écrit. Dans la première phase, tous les expérimentateurs ont reçu un placebo. Dans les deux phases suivantes, après randomisation, 32 expérimentateurs du groupe d'intervention ont reçu *Blatta orientalis* aux dilutions 6C et 30C, et 15 expérimentateurs du groupe témoin ont reçu des globules non médicamentés. Un maximum de 12 doses a été administré dans toutes les phases. Les symptômes et les signes manifestés ont été notés par les expérimentateurs sur un format structuré, élaboré par les maîtres d'expérimentation, et la compilation et l'analyse des données ont été effectuées dans la cellule d'expérimentation et de traitement des données**. Résultats :** L'incidence globale des effets pathogéniques est de 0,625, et l'incidence des effets pathogéniques par expérimentateur est de 2,75. Les symptômes pathogéniques ont montré une affinité organique pour la tête, les yeux, le visage, l'abdomen, les organes génitaux féminins, le système respiratoire, les extrémités, le dos et la peau**. Conclusion :** Une étude clinique complémentaire de vérification de la réponse pathogénique induite permettra d'élargir l'utilisation thérapeutique de *Blatta orientalis* potentialisée par voie homéopathique.

Homöopathische pathogenetische Studie mit *Blatta orientalis*: Eine multizentrische, doppelblinde, randomisierte, placebokontrollierte Studie

Hintergrund: Die therapeutische Wirkung von *Blatta orientalis* bei Asthma wurde zufällig entdeckt, doch abgesehen von den Atemwegssymptomen ist über dieses Arzneimittel in der Homöopathie wenig bekannt. Daher wurde eine homöopathische Arzneimittelprüfung durchgeführt. Dies ist der erste Schritt, der die pathogenetische Wirkung des Arzneimittels für den suggestiven Einsatz in einem klinischen Umfeld umfasst. **Ziel:** Ermittlung der pathogenetischen Reaktion von *Blatta orientalis* bei gesunden Prüfern. **Methoden:** Eine multizentrische, randomisierte, doppelblinde, placebokontrollierte Studie wurde an drei Zentren des Central Council for Research in Homoeopathy durchgeführt. Die Studie wurde an 47 augenscheinlich gesunden Prüfern nach Einholung ihrer schriftlichen Einverständniserklärung durchgeführt. In der ersten Phase erhielten alle Prüfer ein Placebo. In den folgenden zwei Phasen erhielten nach der Randomisierung 32 Prüfer der Interventionsgruppe *Blatta orientalis* in den Potenzen 6C und 30C, und 15 Prüfer der Kontrollgruppe erhielten unmedikamentöse Globuli. In allen Phasen wurden maximal 12 Dosen verabreicht. Die aufgetretenen Symptome und Anzeichen wurden von den Prüfern in einem strukturierten Format dokumentiert, das von den Prüfleitern ausgearbeitet wurde, und die Datenerfassung und -analyse erfolgte in der Prüf- und Datenverarbeitungszelle**. Ergebnisse:** Die Gesamtinzidenz pathogenetischer Effekte beträgt 0,625, die Inzidenz pathogenetischer Effekte pro Prüfer 2,75. Pathogenetische Symptome zeigten eine

Organaffinität zu Kopf, Augen, Gesicht, Bauch, weiblichen Genitalien, Atemwegen, Extremitäten, Rücken und Haut. **Schlussfolgerung:** Weitere klinische Verifizierungsstudien der hervorgerufenen pathogenetischen Reaktion sollen den therapeutischen Einsatz von homöopathisch potenziertem *Blatta orientalis* erweitern.

ब्लाटा ओरिएंटलिस का होम्योपैथिक रोगजनक परीक्षण: एक बहुकेंद्रीय, डबल ब्लाइंड, रैंडमाइज़्ड, प्लेसीबो-नियंत्रित परीक्षण

पृष्ठभूमि: *ब्लाटा ओरिएंटलिस* का चिकित्सीय प्रभाव अस्थमा में संयोगवश पाया गया लेकिन, श्वसन संबंधी लक्षणों के अतिरिक्त इसके रोगजनक प्रभावों की पर्याप्त जानकारी उपलब्ध नहीं है। किसी भी औषधि के नैदानिक उपयोग हेतु परीक्षण उसका प्रथम चरण होता है, जिसके माध्यम से दवा के रोगजनक प्रभावों का स्पष्ट निर्धारण किया जाता है। **उद्देश्य:** स्वस्थ मानव परीक्षक पर *ब्लाटा ओरिएंटलिस* की रोगजनक प्रतिक्रियाओं का अध्ययन करना। **तरीके:** केंद्रीय होम्योपैथी अनुसंधान परिषद के तहत तीन केंद्रों पर एक बहुकेंद्रीय, रैंडमाइज़्ड, डबल ब्लाइंड, प्लेसीबो-नियंत्रित परीक्षण किया गया। लिखित सूचित सहमति प्राप्त करने के बाद 47 स्पष्ट रूप से स्वस्थ परीक्षकों को इस अध्ययन में सम्मलित किया गया। पहले चरण में, सभी परीक्षकों को प्लेसीबो दिया गया। बाद के दो चरणों में, रैंडमाइज़ेशन के बाद, इंटरवेंशन समूह में 32 परीक्षकों को 6C और 30C पोटेंसी में *ब्लाटा ओरिएंटलिस* दिया गया, और कंट्रोल समूह में 15 परीक्षकों को बिना दवा वाली ग्लोब्यूल्स दी गईं। सभी चरणों में अधिकतम 12 खुराकें दी गईं। **परिणाम:** रोगजनक प्रभावों की कुल घटना 0.625 रही, और प्रति परीक्षक रोगजनक प्रभावों की घटना 2.75 रही। रोगजनक लक्षणों ने सिर, आँख, चेहरे, पेट, महिला जननांगों, श्वसन तंत्र, हाथ-पैरों, पीठ और त्वचा के प्रति विशेष आत्मीयता दिखाई। **निष्कर्ष:** प्राप्त रोगजनक प्रतिक्रियाओं के आगे के नैदानिक सत्यापन अध्ययन से होम्योपैथिक रूप से शक्तिशाली *ब्लाटा ओरिएंटलिस* के चिकित्सीय उपयोग का विस्तार संभव होगा।

Ensayo patogénico homeopático de *Blatta orientalis*: Un ensayo multicéntrico, doble ciego, aleatorizado y controlado con placebo

Antecedentes: El efecto terapéutico de *Blatta orientalis* en el asma se descubrió accidentalmente, pero, aparte de los síntomas respiratorios, no se conoce mucho sobre este fármaco a través de pruebas en homeopatía. Por lo tanto, se llevó a cabo la prueba de un fármaco homeopático, que es el primer paso que incluye el efecto patogénico del fármaco, para su uso sugestivo en un entorno clínico. **Objetivo:** Obtener la respuesta patogénica de Blatta orientalis en probadores humanos sanos. **Métodos:** Se realizó un ensayo multicéntrico, aleatorizado, doble ciego y controlado con placebo en tres centros del Consejo Central para la Investigación en Homeopatía. El ensayo se realizó en 47 probadores aparentemente sanos tras obtener su consentimiento informado por escrito. En la primera fase, a todos los probadores se les administró un placebo. En las dos fases siguientes, tras la aleatorización, a 32 probadores del grupo de intervención se les administró *Blatta orientalis* en potencias 6C y 30C, y a 15 probadores del grupo control se les administraron glóbulos sin medicación. Se administró un máximo de 12 dosis en todas las fases. Los síntomas y signos manifestados fueron anotados por los probadores en un formato estructurado, elaborado por los maestros

de prueba, y la recopilación y el análisis de los datos se realizaron en la celda de prueba y procesamiento de datos. **Resultados:** La incidencia global de efectos patogénicos es de 0,625 y la incidencia de efectos patogénicos por probador es de 2,75. Los síntomas patogénicos han mostrado afinidad orgánica por la cabeza, los ojos, la cara, el abdomen, los genitales femeninos, el sistema respiratorio, las extremidades, la espalda y la piel. **Conclusión:** Un estudio de verificación clínica adicional de la respuesta patogénica obtenida ampliará el uso terapéutico de *Blatta orientalis* potenciada homeopáticamente.

东方蜚蠊 (*Blatta orientalis*) 的顺势疗法致病试验：一项多中心、双盲、随机、安慰剂对照试验

背景：东方蜚蠊对哮喘的治疗作用是偶然发现的，但除了呼吸道症状外，人们对其作为顺势疗法药物的疗效知之甚少。因此，进行了顺势疗法药物验证，这是第一步，包括药物的致病作用，以便在临床环境中提出使用建议。**目的**：**引出**东方蜚蠊对健康人类验证者的致病反应。**方法**：**在**顺势疗法中央研究委员会下属的三个中心进行了一项多中心、随机、双盲、安慰剂对照试验。在获得 47 **名看似健康的**验证者的书面知情同意后，对他们进行了试验。在第一阶段，所有验证者都服用了安慰剂。在随后的两个阶段中，随机分组后，干预组的 32 **名**验证者服用 6C **和** 30C **效力的**东方蜚蠊，对照组的 15 **名**验证者服用未用药的球状药水。所有阶段最多服用 12 剂。验证人员将所表现出的症状和体征记录在结构化的格式上，验证主管进行详细说明，并在验证兼数据处理单元进行数据整理和分析。**结果**：**致病效**应的总体发生率为0.625，**每位**验证人员的致病效应发生率为2.75。**致病症状与**头部、眼部、面部、腹部、女性生殖器、呼吸系统、四肢、背部和皮肤等器官密切相关。**结论**：对诱发的致病反应进行进一步的临床验证研究，将扩大顺势疗法增效东方蜚蠊的治疗应用。