

ORIGINAL ARTICLE

A multicentric, double-blind randomized, homoeopathic pathogenetic trial of *Caesalpinia bonducella*

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Objective: To elicit the pathogenetic response of *Caesalpinia bonducella* in homoeopathic potencies on healthy human volunteers.

Methodology: The drug *Caesalpinia bonducella* was proved by the Central Council for Research in Homoeopathy (CCRH) through randomized, double-blind, placebo-controlled design. The proving was conducted at three centres. The drug was proved in 6 & 30 centesimal potencies on 50 apparently healthy volunteers, declared eligible after their pre-trial medical examinations by the medical specialists and routine laboratory investigations. In first phase of proving, provers were given 56 doses of placebo divided in 04 doses per day for 14 days. In next two phases, 56 doses of pre-selected potencies or placebo as per the randomization were administered in divided doses same as in first phase. The symptoms manifested during the trial period were noted down by the provers and elaborated by the Proving Masters. The generated data of the drug from all three centres were compiled at proving-cum-data processing cell of CCRH headquarters after de-coding.

Observations: Out of 34 provers who were on actual drug trial, only 12 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 *Caesalpinia bonducella* and will benefit the research scholars and clinicians. The generated symptoms of this drug will carry more value when verified clinically.

Keywords: homoeopathy; pathogenetic effect; homoeopathic pathogenetic trial; drug proving; *Caesalpinia bonducella*

INTRODUCTION

Caesalpinia bonducella (Nata) is a well known wild shrub of India containing excellent medicinal properties. The medicinal properties of the plant have been known from the ancient times. The root, bark, leaves and seeds of the shrub are used in medicine. The seeds are considered to be "very hot and dry" and useful in

dispersing swellings, arresting haemorrhage, febrifuge, anti-periodic and warding off infectious diseases.¹

Botanical Name	: <i>Caesalpinia bonducella</i> (Linn.) Roxb.
Synonym	: <i>Caesalpinia crista</i> Linn., <i>Guilandina bonducella</i> Linn. <i>Caesalpinia bonducella</i> (Linn) Flem.
Family ²	: Caesalpinaceae
Common names	:
Hindi	: Karanju
Sanskrit	: Kuberakshi
Bengali	: Nata karanja
Tamil	: Kazharshikkay
Persian	: Khyae-i- iblis

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(Devil's testicle)
English : Bonduc nut, Fever nut, Physic nut

"Bonducella" the name of the species is derived from the Arabic word "Bonduce" meaning a "little ball" which indicated the globular shape of the seed.³

Description

A climbing prickly shrub, extending up to 15 m in height, with branchlets glossy, black, armed with hooked and straight, hard yellow prickles at the base of pinnae and elsewhere. Leaves: pinnate, 30 to 60 cm long; petioles prickly; stipules in the form of a pair of reduced pinnae at the base of the leaf, each furnished with a long mucronate point; pinnae 6-11 pairs 5 to 7.5 cm long, stalked, coriaceous, elliptic-oblong, base rounded to acute, apex mucronate, with upper surface glabrous, shining, lower surface puberulous, dull. Inflorescence: 30-60 cm long, axillary and terminal raceme. Flowers: yellow, fragrant, dense at the top of raceme, lax downwards, pedicels 5 to 8 mm, brown downy; bracts squarrose, linear, acute, 1 cm long, fulvous-hairy, calyx 5, corolla 5, stamens 10. Fruit: a pod, dark brown to black, shortly stalked, oblong, 5 to 7.5 cm long and 4.5 cm wide, densely armed on the faces with wiry prickles. Seed: 1 or 2, black, orbicular or ovoid to reniform, beaked and hard.⁴

Distribution

This shrub is found throughout India up to 2000 m from sea level; most common along the sea-coast of West Bengal, southern India and up to 850 m on the hills.⁴

Part used in Homoeopathy: Seed.⁴

Dr. Kali Kumar Bhattacharyya of Gouripore, Assam proved this drug and he published an account of proving in Bengali Monthly Homoeopathic Journal, *Hahnemann*, in the month of *Baisakh*, 1331. The extended provings of the drug have not been made.¹ Therefore, a systematic Homoeopathic Pathogenetic Trial (HPT) of the drug in homoeopathic potencies was necessary to elicit its pathogenetic power which was carried out by Central Council for Research in Homoeopathy (CCRH) as per its approved protocol.

The seeds are tonic; useful in asthma and in snake-bite. Oil from seeds is an emollient which is used as embrocation to remove freckles from the face and for stopping discharges from the ear.^{2,5,6}

Seeds contain bitter substance furanoditerpenes, phytosterinin, bonducellin, bonducin, saponin, aspartic acid, arginine, citrulline and β -carotene, β -sitosterol,

flavonoids, fatty oil 20-24%, starch, sucrose, two phytosterols; bitter amorphous glycoside bonducin can be isolated from the oil.^{5,6,7}

The crude extract of *Caesalpinia bonducella* and its fractions have been found to be antibacterial, antifungal, antispasmodic and possess Ca^{++} antagonistic properties.⁸

The ethanolic extract of *Caesalpinia bonducella* seed kernel possesses potent antipyretic⁹ and antifilarial activity¹⁰. The aqueous extract of *Caesalpinia bonducella* produced significant anti-ulcer and anti-secretory effects.¹¹

The methyl extract of *Caesalpinia bonducella* exhibited significant antitumor and antioxidant activity in Ehrlich ascites carcinoma bearing mice.¹² In an investigation it was revealed that the Petroleum Ether extract of *Caesalpinia bonducella* possessed anticonvulsant activity.¹³

OBJECTIVE

To elicit the pathogenetic response of *Caesalpinia bonducella* on apparently healthy human volunteers in homoeopathic potencies.

MATERIALS AND METHODS

Study Design

The study was a randomized, double-blind, placebo controlled trial.

Participants & settings

The proving of this drug was conducted in 2007-08 at Drug Proving Research Unit of Homoeopathy (DPRU), Kolkata (West Bengal) and Homoeopathic Drug Research Institute (HDRI), Lucknow (Uttar Pradesh) and in 2008-09 at Drug Proving Unit (DPU), Bhubaneswar (Orissa). The study was conducted according to the Drug Proving Protocol of CCRH approved by the Ethical Committee of the Council.

Selection of Provers: Applications from 15-20 volunteers from each Drug Proving Centre were invited from apparently healthy, males & females between the age group of 18-50 years through notices on notice boards of the Institute/Unit/College. The In-charge of the Institute/Unit, Proving Master/Proving Associate, teachers motivated the students & staff of the Homoeopathic Medical College to participate in the Proving Programme.

Volunteers of 18 to 50 years of age, both males and females and apparently healthy, intelligent enough

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to record the subjective symptoms generated during proving were included in the trial. The assessment of health status of the volunteers was done through Pre-trial Medical Examination (PME), carried out by General Physicians, Psychiatrists, Ophthalmologists, ENT Specialists, Dermatologists, Gynaecologists and Radiologists. The routine laboratory investigations of the volunteers were done at the study centres to ascertain their health status. After recommendation of experts, 50 healthy volunteers (24 males & 26 females) were enrolled in the Homoeopathic Drug Proving Programme.

Volunteers showing any psychical or physical symptoms requiring any kind of medical treatment were excluded from the study.

'Written informed consent' from each volunteer was obtained before starting the proving. Volunteers were well informed about the aim & objective of the programme and risk & benefits of participation in Prover's Information Sheet.

Sample size

According to the Drug Proving Protocol of the Council, there should be at least 15 volunteers at one centre, 30% of whom will act as control. As the study was conducted at three centres and consisted of 50 volunteers, 15 volunteers were enrolled at DPRU, Kolkata, 15 volunteers at HDRI, Lucknow and 20 volunteers at DPU (H), Bhubaneswar. Therefore, out of 50 volunteers, 34 were on verum and 16 were on placebo. All the volunteers completed the Proving Programme successfully.

Intervention

Drug

Caesalpinia bonducella was procured from a GMP certified Homoeopathic Drug manufacturer in India, in 6C and 30C potencies, in 100 ml. sealed bottles of each dilution. Globules of number 30 were medicated with these attenuations at the CCRH headquarters office.

Placebo

Placebo was made up of unmedicated globules (number 30) moistened with unmedicated dispensing alcohol (unsuccussed) and was therefore indistinguishable from verum.

Randomization and Blinding

All the volunteers were assigned code numbers and the coded drugs of different potencies/ placebo were supplied in separate glass phials bearing code numbers of the respective volunteer; keeping both

Provers and Proving Master blind about what Prover was consuming (drug or placebo). The codes were allotted to each volunteer and randomization was done at CCRH headquarters.

The drug was sent to the proving centres in coded phials (verum) along with placebo (control).

Methodology of Proving

The study consisted of three phases. In each phase, 56 doses of drug or placebo were administered, divided into 4 doses/day for fourteen days, if no symptom arises.

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

Phase-II : In 2nd phase, the proving was conducted with 6C potency of the drug.

Phase-III : In 3rd phase, the proving was conducted with 30C potency of the drug.

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

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

If sign(s)/ symptoms(s) appeared

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

After disappearance of sign(s) and/or symptom(s)

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

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

Each volunteer was interrogated by the Proving Master to verify the sign(s) and/or symptom(s) recorded by the volunteer. The symptoms recorded in 'Prover's Day Book Proforma' were verified by the Proving Master and completed through further interrogation with the provers in respect to their location(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 volunteers were referred for specific laboratory investigation(s) to rule out any pathological cause of appearance of symptom(s). Since laboratory tests were performed to identify any correlation between the subjective and objective changes during the course of proving, the expert opinion of the honorary consultant(s) was obtained, wherever needed.

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

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

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

The same procedure was followed for the 3rd phase.

After completion of trial of all potencies, the volunteers 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 at the Council's headquarters by the Drug Proving-cum-Data Processing Cell. After decoding, the sign(s) and/or symptom(s) generated by the volunteers kept on the drug were separated from those generated by the volunteers kept on placebo.

Management of adverse effects:

A vial of *Camphora* was sent with each quota to each centre as antidote as it is believed that *Camphora* can antidote nearly every vegetable medicine.¹⁴ Proving Master used to give antidote to the volunteer if symptoms continue for a long time or intensity was more to cause discomfort. Proving Master was also directed to take advice of honorary consultants and to get laboratory investigations done, if required.

Pathogenetic effects

Pathogenetic effects (Proving symptoms) are defined as all changes in clinical events and laboratory findings reported by the volunteers during a Homoeopathic Pathogenetic Trial and recorded in the final report. The incidence of pathogenetic effects per volunteer is defined as the total number of findings observed in the trial divided by the total number of provers.¹⁵

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

At Drug Proving Unit (H), Bhubaneswar, out of 14 volunteers on trial drug, 06 volunteers reported symptoms (42.86%). At Drug Proving Research Unit of Homoeopathy (DPRU), Kolkata, out of 10 volunteers on trial drug, 03 volunteers reported symptoms (30.00%) and also, at Homoeopathic Drug Research Institute for Homoeopathy (HDRI), Lucknow, out of 10 volunteers on trial drug, only 03 volunteers reported symptoms (30.00%). During the pathogenetic trial, out of 34 volunteers who were in verum group, only 35.29% (n=12) volunteers reported symptoms consequent upon the administration of the drug. Incidence in this proving was 2.08 findings per volunteer. The drug *Caesalpinia bonducella* was able to produce symptoms in both the potencies i.e. 6C and 30C. Twenty five symptoms

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were produced by the Provers in verum group in 2nd & 3rd phases. Twelve symptoms were produced in 30C potency and thirteen symptoms were produced in 6C potency. (Fig. 1) No adverse effect was observed during the trial, hence, antidote (*Camphora*) was not used.

The following symptoms were manifested during the drug proving:

Head

- Headache with vertigo, *agg.* after watching T.V. at night. (1,6C)* (22,1)[†]
- Heaviness of head. (1,6C) (9,1)
- Severe throbbing pain in whole head with chilliness; *amel.* pressure, tight bandage. (1,6C) (45,1)

Eyes

- Redness and swelling with pain in right upper eyelid and lachrymation followed by pain in left eyelid with headache. (1,6C) (16,13)
- Painful red eruptions on upper eyebrow; throbbing pain, *agg.* bending head forward; *amel.* bending head backward. (1,30C) (32,7)

Nose

- Acrid nasal discharge with redness and burning sensation at tip of nose, *agg.* morning, touch. (1,30C) (43,5)
- Running nose. (1,30C) (16,3)
- Coryza with severe sneezing, *agg.* morning. (1,30C) (29,5)

Face

- Swelling of right parotid gland with severe pain. (1,6C) (45,8)

Mouth

- Bad taste in mouth. (1,6C) (48,6)
- Swelling of gums. (1,6C) (4,2)
- Ulcer on lower lip with burning sensation, *agg.* eating. (1,30C) (29,5)

Throat

- Pain in throat with difficulty in deglutition, *agg.* morning; *amel.* drinking tea. (1,6C) (24,5)
- Sore throat. (1,30C) (22,3)

External throat

- Red, herpetic eruptions with burning sensation in right side of external throat extending upto the mandible, *agg.* touch, followed by pus formation and later blackening of eruptions. (1,30C) (5,12)

Stomach

- Nausea with loss of appetite. (1,6C) (48,6)
- Nausea with vomiting in early morning, *agg.*, sitting; *amel.* open air. (1,30C) (32,1)

Rectum

- Diarrhoea: **yellowish**^{1‡}, watery, gushing stool with pain in abdomen from morning to afternoon. (1,30C) (32,1)

Cough

- Spasmodic dry cough, *agg.* at night, during sleep. (1,30C) (22,4)
- Cough with expectoration. (1,30C) (16,8)

Back

- Red, hard nodular painful swelling on left scapula. (1,6C) (38,14)
- Red, itching eruptions on back mainly on scapular region, *agg.* from contact of clothes. (1,6C) (8,2)

Extremities

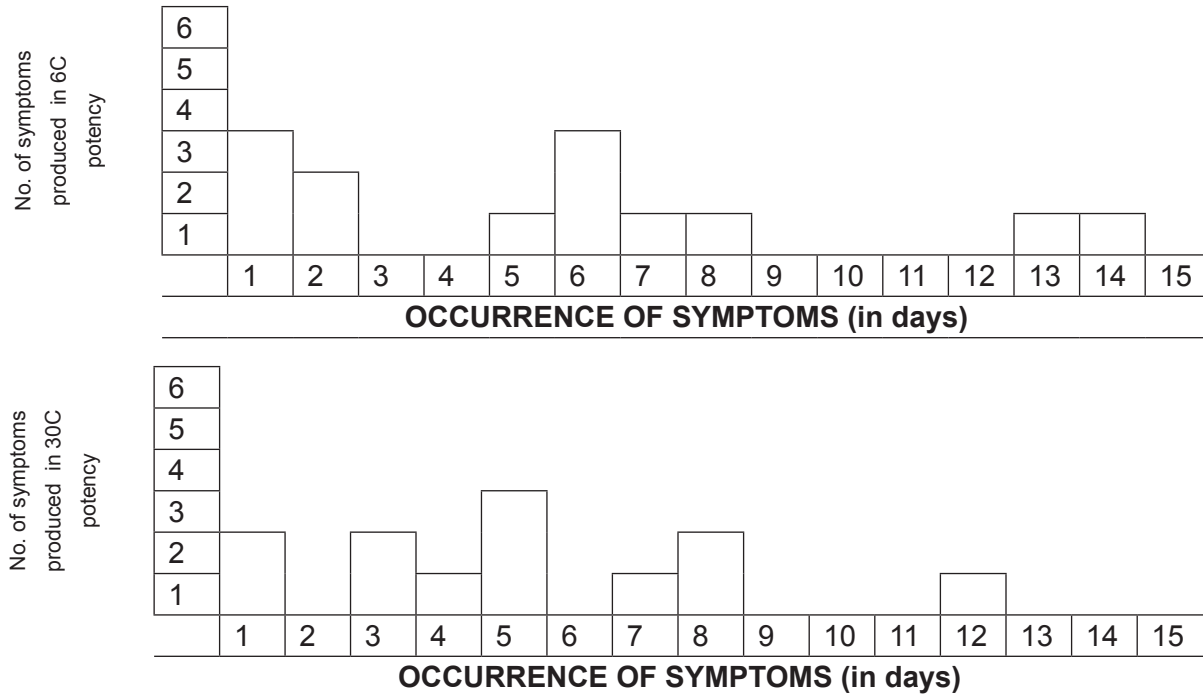
- Mild loss of sensation with numbness of left index finger. (1,6C) (36,7)
- Itching and burning sensation in calf muscles with redness, *agg.* bathing in cold water. (1,30C) (53,8)

*In the first parenthesis, the 1st number given after every symptom denotes number of volunteers who produced that particular symptom and 2nd number denotes potency used.

[†]In second parenthesis, the 1st number denotes number of doses of the drug after which that particular symptom was produced and the 2nd number denotes the duration (in days) for which the symptom lasted.

[‡]Symptoms produced during the pathogenetic trial of the drug were compared with the homoeopathic literature cited in the reference and those symptoms which were found in the literature, are shown in **bold**, superscribed with a numerical that refers to the respective literature.

Figure-1: Number of symptoms produced by 6C and 30C potencies of *Caesalpinia bonducella* and their duration in



Fever

- **Fever with chill**¹, *amel.* noon. (1,6C) (45,6)

Symptoms produced by provers in Control (Placebo) group

- Head** Hammering pain in both temporal regions of head, *agg.* reading; *amel.* lying down, closing eyes. (1)^Φ(36,3)^Φ Headache.(2 (40,2) (16,1)^{ΦΦ}
- Eye** Bruised pain in left eye extending to left side of forehead. (1)(32,5 & 36,3)^Ψ
- Throat** Throat pain with coryza; nose block after eating ice-cream. (1) (13,7)
- Stomach** Hunger with weakness. (1) (8,2)
Nausea and mild eructation after food. (1) (14,3)
- Abdomen** Cutting pain in whole upper abdomen. (1) (24,1)
- Rectum** Watery diarrhea, *agg.* morning. (1) (24,2)

Chest

Chest pain. (1)(12,2)

Extremities

Itching of both legs and feet without eruptions. (1) (8,1)

Sleep

Drowsiness. (1) (8,3 & 24,1)

Fever

Fever with coryza and cough after drenching in rain. (1)(32,21)

Skin

Itching of whole body with red macular eruptions, *agg.* heat; *amel.* cold air. (1) (1,6 & 3,32)

Generalities

Internal heat feeling everywhere. (1) (1,6 & 3,41)

DISCUSSION

All the symptoms of the drug were new except two viz. “yellowish stool” and “fever with chill” which were produced during previous proving as compiled by Dr. S.C. Ghose¹. Some symptoms like of eyes, external throat, cough, back etc. lasted for many days; this shows the drug has affinity towards these regions. Some symptoms appeared on administration after few doses, like swelling of gums appeared after

^Φ The number given in first parenthesis denotes number of volunteers who produced that particular symptom.
^Φ In second parenthesis, the 1st number denotes number of doses after which that particular symptom was produced and the 2nd number denotes the duration (in days) for which the symptom lasted.
^{ΦΦ} In third parenthesis, symptom produced in second prover is shown.
^Ψ Symptom produced two times in same prover shown in single parenthesis with no. of doses and duration.

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administration of 4th dose and symptom of external throat appeared after administration of 5th dose which lasted for 12 days. The symptoms developed in Control (placebo) group were different from those developed by verum group.

CONCLUSION

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

Conflict of interest: There is no conflict of interest.

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उद्देश्य : स्वस्थ मानक स्वयंसेवकों पर होम्योपैथी पोटेंसी में सेसलपिनिया बोन्दुसेला के रोगमूलक प्रतिक्रियाओं को उल्लेखित करना।

पद्धति : केन्द्रीय होम्योपैथी अनुसंधान परिषद् द्वारा सेसलपिनिया बोन्दुसेला औषधि का प्रमाणन एक यादृच्छिक, डबल ब्लाइंड प्लासिबो नियंत्रित पद्धति द्वारा किया गया। परिषद् के तीन केन्द्रों पर यह प्रमाणन कार्य किया गया। इस औषधि का प्रमाणन 6 और 30 शतांश पोटेंसियों में, स्वास्थ्य विशेषज्ञों द्वारा जाँच एवं सामान्य प्रयोगशाला परीक्षणों में योग्य पाये गये 50 स्वस्थ स्वयं सेवकों पर किया गया। प्रमाणन को प्रथम अवस्था में प्लासिबो की 56 खुराकें, 4 खुराकें प्रतिदिन के हिसाब से 14 दिनों तक स्वयंसेवकों को दी गई।

अगली दो अवस्थाओं में, यादृच्छिकता के आधार पर पूर्व चयनित पोटेंसियों या प्लासिबो की 56 खुराकें प्रथम अवस्था के अनुसार ही दी गई। परीक्षण काल के दौरान उत्पन्न हुए लक्षणों को स्वयंसेवकों द्वारा उल्लेखित एवं प्रमाणन मास्टरो के द्वारा विस्तारित किया गया। सभी केन्द्रों से प्राप्त औषधि के आंकड़ों को परिषद् मुख्यालय स्थित प्रमाणन-सह-आँकड़ा परिष्करण कक्ष में डी-कोडिंग के उपरांत संकलित किया गया।

टिप्पणियाँ : वास्तविक रूप से औषधि परीक्षण में सम्मिलित 34 प्रमाणकों में से 12 प्रमाणकों ने लक्षणों को प्रदर्शित किया। दोनों पोटेंसियों में शरीर के प्रत्येक भाग पर कम या अधिक रूप से यह औषधि लक्षणों को उत्पन्न करने में सफल रही।

निष्कर्ष : प्रमाणन परीक्षण के दौरान सामने आये रोगमूलक प्रतिक्रियात्मक व्यवहार सेसलपिनिया बोन्दुसेला के औषधीय उपयोग के क्षेत्र को विस्तारित करते हैं जो कि अनुसंधान विद्वानों और चिकित्सकों के लिए भी अत्यन्त लाभकारी है। इस औषधि से सत्यापन होने पर और अधिक महत्त्व होगा।

खोजशब्द : होम्योपैथी, रोगमूलक प्रभाव, होम्योपैथी रोगमूलक परीक्षण, औषधि प्रमाणन, सेसलपिनिया बोन्दुसेला