

# Efficacy of predefined homoeopathic medicines in the treatment of warts: Study protocol of double blind randomised placebo controlled trial

Central Council for Research in Homoeopathy

## Abstract

**Background and Objectives:** The literature cites a large number of homoeopathic medicines for the treatment of warts. Studies on warts are based on experiences of individual practitioners and do not give specific factors, which are responsible for making a successful prescription for the treatment of warts. The present study was designed as a multicentric randomised, double-blind, placebo-controlled trial to evaluate response to homoeopathic treatment for the disappearance or resolution of warts and to validate the symptoms of the pre-identified 09 drugs (*Antimonium crudum*, *Calcarea carbonicum*, *Causticum*, *Dulcamara*, *Natrum muriaticum*, *Nitric acidicum*, *Ruta graveolens*, *Sulphur* and *Thuja occidentalis*) on clinical outcome in warts. **Materials and Methods:** The study would be conducted at eight centres of the Central Council for Research in Homoeopathy, where patients requiring any of the predefined medicines for warts would be randomised to Homoeopathy or placebo group using a computer-generated randomisation chart. The selected medicine would be prescribed first in 6C potency and dosage and subsequent potency as per the requirement of the case. Outcome is based on the percentage of warts completely disappeared assessed fortnightly for 6 months. **Discussion:** The study intends to combine randomised controlled trial with validation of symptoms of the pre-identified drugs in warts. The symptoms of verum group in each case successfully treated would be compared with that in the control group. The study would aid in assessing treatment efficacy and identifying the symptomatology on the basis of which successful prescriptions have been made.

**Keywords:** Prognostic factor research, Randomised controlled trial, Symptom validation, Warts

## INTRODUCTION

Warts are common dermatological disorders for which patients frequently seek homoeopathic treatment. In an observational study, results of *Thuja occidentalis* in verruca vulgaris, verruca plana and verruca plantaris and effect of *Ruta graveolens*, *Calcarea carbonicum*, *Antimonium crudum*, *Causticum*, *Nitric acid*, *Natrum muriaticum* and *Opium* on different types of warts have been reported.<sup>[1]</sup> In a double-blind, placebo-controlled clinical trial from 1995 to 1997, the effectiveness of *Ruta*, *Nitric acid*, *Dulcamara*, *Causticum* and *Thuja* on different types of warts has been reported.<sup>[2]</sup> However, two randomised, double-blind, placebo-controlled clinical trials showed no apparent difference between the effect of homoeopathic therapy and placebo in the treatment of warts on hands in children<sup>[3]</sup> and plantar warts.<sup>[4]</sup> A recent study on 200 patients reported that, in 88% of cases, remission started within 1 month and complete remission was seen by 3 months.<sup>[5]</sup>

In Homoeopathy, warts are classified under one-sided disease, i.e. diseases which have very few expressions in terms of symptoms. Under this, it is further categorised under external-local maladies.<sup>[6]</sup> Warts are recognised as an expression of sycotic miasm in homoeopathic philosophy. Although warts are local diseases, they are treated with internal remedy, based on comprehensive understanding of the patient.<sup>[6]</sup> The literature cites a large number of homoeopathic medicines for the treatment of warts. Identifying a correct remedy which can correct this internal dyscrasia is a challenge for a routine prescriber.

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All the reported studies are unicentric based on experiences of individual practitioners and do not give specific factors, which are responsible for a successful prescription for the treatment of warts.

The Central Council for Research in Homoeopathy (CCRH) aims to undertake research that can be translated into a successful clinical practice. With this background, the present study has been designed as a multicentric randomised, double-blind, placebo-controlled trial to evaluate response to homoeopathic treatment for disappearance or resolution of warts and to validate the symptoms of the pre-identified nine drugs on clinical outcome in warts.

The study protocol is in accordance with the Helsinki declaration on human experimentation.<sup>[7]</sup> Requisite clearance of the Ethical Committee and Scientific Advisory Committee of CCRH had been obtained before undertaking the study. The ethical approval of the study had been obtained from the Ethical Committee of the Council vide letter no: 1-3/2017-18/CCRH/TECH/CR/WARTS/1372, dated 24.8.17. The trial is registered with the Clinical Trials Registry of India (CTRI), namely CTRI/2018/12/016672 (registered on: 14/12/2018).

## Objectives

### Primary objective

To evaluate response to homoeopathic treatment for disappearance or resolution of warts.

### Secondary objective

To validate the symptoms of the following pre-identified nine drugs on the successful clinical outcome on warts:

1. *Antimonium crudum*
2. *Calcarea carbonicum*
3. *Causticum*
4. *Dulcamara*
5. *Natrum muriaticum*
6. *Nitric acidicum*
7. *Ruta graveolens*
8. *Sulphur*
9. *Thuja occidentalis*.

## MATERIALS AND METHODS

### Settings

The study shall be conducted at different centres of the CCRH located at Agartala, Gudivada, Jaipur, Kolkata, Kottayam, Mumbai, Noida and Puri. The study will be conducted in special dermatology clinics in these research centres. The dermatology clinics are managed by trained homoeopathic practitioners with research experience. The clinics provide routine outpatient department (OPD) care to patients suffering from dermatological disorders using homoeopathic medicines only.

### Eligibility criteria

Patients are eligible if they are in the age group of 18–65 years, of either gender, presenting with cutaneous warts. Patients with anogenital or plantar warts would however, be excluded from

the study. Patients with bowenoid papulosis, focal epithelial hyperplasia or seborrhoeic keratosis, past history of skin cancer, having undergone treatment with immune-modulating oral medications such as corticosteroids in the past 4 weeks, patients already on homoeopathic treatment for any disease condition, self-reporting cases of HIV, pregnant and lactating women or those with advance disease of vital organs would be excluded from the study.

In all the patients who give consent for participation and fulfil the inclusion criteria, a detailed case taking would be done. Indicated homoeopathic medicine as per symptom similarity would be identified on the basis of the totality of symptoms. Only cases corresponding to the above mentioned pre-identified homoeopathic medicines will be enrolled in the study and randomised. The cases not falling in the above mentioned drug list will not be enrolled in the study. They would be provided standard treatment in the dermatology OPD, and their data will be maintained separately from the study data.

### Randomisation and group allocation

Cases enrolled in the study would be randomised into two groups as follows: Groups A and B for each drug with a 1:1 allocation based on computer-based SPSS software. The enrolment number of the patients will be used for the purpose for randomisation and will be maintained for all follow-up visits. Allocation will be concealed till the primary end point is analysed. The allocation codes will be kept with the Principal investigator (PI) and co-investigator (Co-I) at the CCRH headquarters. The randomisation chart allocating patients to the two groups will be sent to the study site along with the study medicines. One group will be administered active drug and the other will be placebo.

### Blinding

The study will be a double-blind study, where the investigators at the study sites and the patients will be kept blind about the group allocation. Un-blinding or breaking of the randomisation codes will be done by the study PI at the headquarters after the study has been completed and the database is frozen. The statistician analysing the data will also be kept blind of the allocation of the groups while analysing the data.

### Intervention and follow-up

The drugs identified for the trial shall be procured from a Good Manufacturing Practices (GMP)-compliant pharmaceutical firm. 83.1%v/v ethyl alcohol (used as a vehicle to prepare homoeopathic medicines) will be used as placebo. The placebo will be dispensed in sugar globules of standard size 30 identical to the verum in appearance and taste.

The selected medicine would be initially prescribed in 6C potency at the start of the treatment. Dosage schedule will be as per the requirement of the case. During the period of the study, the potency would be raised sequentially as per the need of the case, in pursuance with the homoeopathic principles. Cases would be followed up at fortnightly interval till complete disappearance of all warts or for 6 months, whichever is earlier.

At each follow-up, an assessment would be made of change in the number and size of warts, and any change in associated symptoms. Digital photograph of the site of warts would be made taking into consideration that identity and privacy of the patient is not compromised at any stage.

The participant timeline for each patient is given in Table 1.

The treatment will be discontinued and patients will be withdrawn early due to non-compliance to treatment or in case of appearance of any adverse drug event.

### Sample size

In the study there are 09 pre-identified drugs and 60 cases will be enrolled at each centre which will be randomized into two groups (30 in drug and 30 in placebo group). As there are 08 study centers, the total sample size for the study will be 480 cases.

### Outcome assessment

Outcome would be the percentage of warts completely disappeared i.e. the number of warts disappeared.

### Data recording and analysis

Data of all cases will be maintained by the PI and the Co-I and will be added in a pre-designed master chart. The case record and follow-up formats have been designed with an intent to capture all symptoms associated with warts relating to the pre-specified drugs, with due consideration to the principles of homoeopathic case taking. There are no leading questions pointing to a specific medicine or group of medicines, yet a broad framework with general questions has been added to ensure that the case is completed in all possible aspects, i.e. both general and particular symptoms.

The copy of complete records of the cases will be sent to the PI at the CCRH headquarters after completion of 6-month follow-up of the case in the study. The master chart would be sent to the CCRH headquarters at the end of the study period.

The study outcome will be analysed according to parametric test for continuous data and non-parametric test for ordinal data. Baseline comparison would be considered for evaluating the randomisation effect. All the statistical results would be reported in 95% confidence interval with confidence level

alpha ( $\alpha$ ) = 0.05. Stratified analysis of the variables potentially associated with healing of warts, namely number, type of warts, pain and age of warts, will be done.

Validation of symptoms would be as per the methods described under prognostic factor research<sup>[8]</sup> for cases treated successfully by homoeopathic medicines.

## DISCUSSION

Warts are frequently considered a one-sided disease with lack of symptoms, and therefore constitutional makeup and other individual characteristics are required for prescription. There has been a long-term experience of homoeopaths that warts disappear when well-indicated medicines covering general and particular symptoms are taken care of during prescription. Therefore, this protocol is designed to prescribe in a similar manner using pre-defined homoeopathic medicines while taking into consideration the basic principles of Homoeopathy; only patients requiring any of the study medicines are included and randomised into treatment and control groups.

The protocol has been developed as per the SPIRIT guidelines<sup>[9]</sup> and shall generate data that can be reported as per the CONSORT guidelines<sup>[10]</sup> and RedHot supplement for reporting randomised trials of Homoeopathy.<sup>[11]</sup> For this study, the drugs were identified on the basis of a literature review and most frequently used in the studies reported. The symptoms related to warts, in particular, and skin complaints, in general, have been identified for validation which would be conducted after the analysis of cases on quantifiable parameters to ascertain the efficacy of treatment.

It has been identified that the best way to assess a causal relationship between cure and medicine is the randomised controlled trial (RCT), but this method is not suited for individual cases. Homoeopathy has a unique opportunity to develop its own scientific identity in achieving evidence-based personalised medicine, whereas RCT evidence fails to serve the needs of the individual patient. We can use accepted scientific methods derived from diagnostic research.<sup>[12]</sup>

An interesting aspect of Homoeopathy is that the prescription is 'personalised:' it fits the patient as a whole, not only the

**Table 1: Participant timeline**

Process	Timeline			
	Day 0	Day 1	Follow-up fortnightly till the disappearance of warts or 6 months, whichever is earlier	At the end of treatment
Screening	√			
Informed consent	√			
Baseline assessment	√			
Randomisation and allocation to group	√			
Intervention		√		
Follow-up			√	
Digital photograph		√	√	√

diagnosis. As individualised medicine is the essence of Homoeopathy and a trending topic in medical research, we should focus more on 'personalised' research, on validating the symptoms that indicate homoeopathic medicines. This is also an answer to the main problem of RCT evidence: it is not personalised. This recent demand for personalised research besides RCT is an excellent opportunity to favour other methods of evidence-based medicine to improve the knowledge in homoeopathic *Materia Medica* and *Repertories*. We can compare the homoeopathic prognostic process with the conventional diagnostic process and use research methods that are common in diagnostic research.<sup>[13]</sup>

This study intends to combine both the approaches, where the symptomatology in individual cases would be assessed and compared with those in the control group, to not only identify and quantify the efficacy, but also to identify the symptomatology on the basis of which successful prescriptions have been made.

RCTs on warts will ensure that the evident results in terms of disappearance of warts are attributable neither to the self-limiting nature of the condition nor to placebo effect. Subsequently, the prescribing symptomatology would be validated.

However, such a strategy will be able to derive statistics if sufficient number of cases under each drug *vis-a-vis* control group are generated. This will further help the profession to draw meaningful symptomatic data to make clinical practice easier by using successful research outcome.

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### Conflicts of interest

None declared.

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**मस्सों के उपचार में पूर्वनिर्धारित होम्योपैथिक दवाओं की प्रभावकारिता का मूल्यांकन करने हेतु एक डबल ब्लाइंड यादृच्छिक प्लासिबो नियंत्रित अध्ययन पर एक प्रोटोकॉल**

**सार**

**पृष्ठभूमि और उद्देश्य:** मस्सों के उपचार हेतु साहित्य बड़ी संख्या में होम्योपैथिक दवाओं का उद्धरण देता है। मस्सों पर किये गए अध्ययन व्यक्तिगत चिकित्सकों के अनुभवों पर आधारित हैं और ऐसे विषिष्ट कारक स्पष्ट नहीं करते जो मस्सा के उपचार के लिए एक सफल नुस्खा बनाने के लिए उत्तरदायी हों। वर्तमान अध्ययन को बहु-केंद्रित यादृच्छिक, डबल ब्लाइंड, प्लासिबो नियंत्रित परीक्षण के रूप में डिजाइन किया गया था जो मस्सों के लुप्त होने या समाधान के लिए होम्योपैथिक उपचार की प्रतिक्रिया का मूल्यांकन करने और पहले से पहचानी गई 09 दवाओं (एंटीमोनियम क्रूडम, कैल्केरिया कार्बोनिक्म, कास्टिकम, डल्कामारा, नेट्रम म्यूरियाटिकम, नाइट्रिक एसिडिकम, रूटा ग्रेवोलान, सल्फर, थूजा ऑसीडेंटलिस) के लक्षणों को मान्य करने के लिए किया गया था।

**सामग्री और तरीके:** अध्ययन केन्द्रीय होम्योपैथी अनुसंधान परिषद् के 8 केंद्रों पर आयोजित किया जाएगा, जहां मस्सा के लिए पूर्वनिर्धारित दवाओं में से आवश्यकता वाले रोगियों को कंप्यूटर द्वारा यादृच्छिककरण चार्ट का उपयोग करके होम्योपैथी या प्लासिबो समूह को यादृच्छिक किया जाएगा। चयनित दवा को पहले 6सी पोटेंसी और बाद में संभावित आवश्यकता के अनुसार मामले में निर्धारित किया जाएगा। परिणाम मस्सा के प्रतिषत पर आधारित हैं जो 6 महीने के लिए पूरी तरह से लुप्त हो गया।

**चर्चा:** अध्ययन का उद्देश्य मस्सों में पूर्वनिर्धारित दवाओं के लक्षणों के सत्यापन के साथ यादृच्छिक नियंत्रण परीक्षण को संयोजित करना है। प्रत्येक मामले में विरम समूह के लक्षणों का उपचार नियंत्रण समूह के साथ तुलना कर किया जाएगा। अध्ययन उपचार की प्रभावकारिता मदद करेगा और उस लक्षण विज्ञान की पहचान करेगा जिसके आधार पर सफल उपचार किये गये हैं।

**Protocole sur une étude randomisée à double insu et contrôlée par placebo pour évaluer l'efficacité des médicaments homéopathiques prédéfinis dans le traitement des verrues.**

**RÉSUMÉ**

**Contexte et objectifs:** La littérature cite un grand nombre de médicaments homéopathiques pour le traitement des verrues. Les études sur les verrues sont basées sur les expériences des praticiens individuels et ne signalent pas les facteurs spécifiques qui sont responsables du succès des médicaments prescrits pour le traitement des verrues. La présente étude a été conçue comme une étude multicentrique randomisée à double insu et contrôlée par placebo pour évaluer la réponse à un traitement homéopathique pour la disparition des verrues, ou comme leur solution, et pour valider les symptômes de 9 médicaments préalablement identifiés, à savoir *Antimonium crudum*, *Calcarea carbonicum*, *Causticum*, *Dulcamara*, *Natrum muriaticum*, *Nitric acidicum*, *Ruta graveolans*, *Soufre* et *Thuja occidentalis*, sur les résultats cliniques dans le traitement des verrues.

**Matériels and méthodes:** L'étude a été menée dans 8 centres du CCRH, où les patients ayant besoin d'un des médicaments prédéfinis pour les verrues ont été répartis de façon aléatoire, à l'aide d'un tableau de randomisation généré par ordinateur, dans un groupe recevant un médicament homéopathique ou dans un groupe recevant un placebo. Le médicament sélectionné a d'abord été prescrit en dilution et dosage de 6C et en dilutions ultérieures selon les exigences du cas. Le résultat est basé sur le pourcentage de verrues ayant complètement disparu. L'évaluation a été effectuée toutes les deux semaines pendant une période de 6 mois.

**Discussion:** L'objectif de l'étude est de combiner l'essai randomisé contrôlé avec la validation des symptômes des médicaments préalablement identifiés dans le traitement des verrues. Les symptômes du groupe verum dans chaque cas traité avec succès ont été comparés à ceux du groupe témoin. L'étude pourrait aider à évaluer l'efficacité du traitement et à identifier la symptomatologie sur la base de laquelle des médicaments réussis ont été prescrits.

## Protocolo de un estudio aleatorizado, controlado con placebo a doble ciego para evaluar la eficacia de los medicamentos homeopáticos predefinidos para el tratamiento de verrugas

### RESUMEN

**Fundamentos y objetivos:** En la bibliografía, se enumera un gran número de medicamentos homeopáticos para el tratamiento de verrugas. Los estudios sobre verrugas se basan en las experiencias de médicos individuales y no ofrecen factores específicos que permitan establecer una prescripción satisfactoria para el tratamiento de las verrugas. El presente estudio se diseñó como un ensayo aleatorizado, controlado con placebo, a doble ciego para evaluar la respuesta al tratamiento para la desaparición o resolución de las verrugas y validar los síntomas de 9 medicamentos preidentificados (*Antimonium crudum*, *Calcarea carbonicum*, *Causticum*, *Dulcamara*, *Natrum muriaticum*, *Nitric acidum*, *Ruta graveolans*, *Sulphur*, *Thuja occidentalis*) como parámetros clínicos para las verrugas.

**Materiales y métodos:** El estudio se realizará en 8 centros del CCRH, en los que se aleatorizarán los pacientes que precisan cualquiera de los medicamentos predefinidos para verrugas a un grupo con homeopatía o un grupo de control con placebo conforme a un gráfico de aleatorización generado por ordenador. Los medicamentos seleccionados se prescribirían primero en la potencia de 6c y después a una dosificación y posterior potencia según necesidades. El resultado se basa en el porcentaje de verrugas completamente eliminadas evaluado cada dos semanas durante 6 meses. percentage of warts completely disappeared assessed fortnightly for 6 months.

**Discusión:** El objetivo del estudio es combinar un ensayo aleatorizado controlado con la validación de síntomas de medicamentos preidentificados para el tratamiento de verrugas. Los síntomas del grupo con el medicamento verdadero de cada caso tratado con éxito se deberán comparar con los del grupo de control. El estudio ha de ayudar a aumentar la eficacia del tratamiento e identificar la sintomatología a partir de la cual se pudieron realizar prescripciones que llevaron al éxito del tratamiento.

*Palabras clave:* Investigación de factores pronósticos, ensayo controlado aleatorizado, validación de síntomas, verrugas

## Protokoll einer randomisiertenplacebokontrolliertenDoppelblindstudie zur Bewertung der Wirksamkeit vordefinierter homöopathischer Arzneimitteln bei der Behandlung von Warzen

### ABSTRAKT

**Hintergrund und Ziele:** In der Literatur findet sich eine große Anzahl homöopathischer Arzneimittel zur Behandlung von Warzen. Studien zur Behandlung von Warzen basieren auf Erfahrungen einzelner Praktiker und geben keine spezifischen Faktoren an, die für eine erfolgreiche Behandlung von Warzen verantwortlich sind. Die vorliegende Studie wurde als multizentrische, randomisierteplacebokontrollierte Doppelblindstudie konzipiert, um den Erfolg einer homöopathischen Behandlung zum Verschwinden oder zur Beseitigung von Warzen zu bewerten und die Symptome der neun zuvor identifizierten Arzneimittel (*Antimonium crudum*, *Calcarea*, *Causticum*, *Dulcamara*, *Natrium muriaticum*, *Nitric acidum*, *Ruta graveolans*, *Sulphur*, *Thuja occidentalis*) im klinischen Verlauf zu validieren.

**Material und Methoden:** Die Studie wurde an acht Zentren des CCRH durchgeführt. Die Patienten, bei denen eines der vordefinierten Arzneimittel für Warzen indiziert war, wurden unter Verwendung einer computergenerierten Randomisierungstabelle nach dem Zufallsprinzip der Homöopathie- oder die Placebogruppe zugeteilt. Die gewählte Arznei wurde zuerst in C 6 und in weiteren Potenzen - entsprechend der Anforderung des Falles - dosiert. Das Ergebnis basiert auf dem Prozentsatz vollständig verschwundener Warzen, was während sechs Monaten alle zwei Wochen kontrolliert wurde.

**Diskussion:** Die Studie beabsichtigt, randomisierte Kontrollstudien mit einer Validierung der Symptome von vorab bestimmten Arzneimitteln gegen Warzen zu kombinieren. Die Symptome der Verumgruppe wurden in jedem Fall erfolgreich behandelt und mit denen in der Kontrollgruppe verglichen. Die Studie würde helfen, die Wirksamkeit der Behandlung zu beurteilen und eine Symptomatik zu identifizieren, auf deren Grundlage erfolgreiche Verordnungen gemacht werden.

## 雙盲隨機安慰劑對照試驗計劃書：評估預先規定順勢療法療劑處理疣的有效性

順勢療法研究中央委員會（CCRH）

### 摘要

**背景和目標：**文獻引述了大量處理疣的順勢療法療劑。對於疣的研究，都是基於個別順勢療法醫生的經驗，而沒有找出特定因素，指向於處理疣的成功處方。本研究是一個多中心、隨機雙盲安慰劑對照試驗，去評估順勢療法治療對於疣的消失或消退的反應，並在臨床治療疣中，確認9隻預先規定療劑（輝銻礦*Antimonium crudum*、碳酸鈣*Calcarea carbonica*、苛性鉀*Causticum*、白英*Dulcamara*、氯化鈉*Natrum muriaticum*、硝酸*Nitric acidicum*、芸香*Rutagraveolans*、硫磺 *Sulphur*、側柏*Thuja occidentalis*）的症狀。

**材料和方法：**研究會在8個CCRH的中心進行，當病人需要任何一隻預先規定的療劑去處理疣時，會透過電腦產生的隨機化圖表，隨機分配至順勢療法或安慰劑組別。被選療劑的第一次處方為6c層級，劑量和隨後的層級都會按個案需要而決定。結果是評估疣完全消退的百分比，每兩星期評估一次，持續6個月。

**討論：**研究旨在結合隨機對照試驗，以及確認預先規定處理疣的療劑之症狀。每一個非安慰劑組別的成功個案之症狀，都會與對照組別的症狀比較。研究將有助評估治療有效性，以及基於成功的處方去分辨症狀學。

**關鍵字：**預後因素研究、隨機對照試驗、症狀確認、疣。