

# Protocol for efficacy of individualised homoeopathic medicine in cases of wrist ganglion: A prospective, parallel arm, randomised, double-blind, placebo-controlled trial

Central Council for Research in Homoeopathy

## Abstract

**Background and Objectives:** Wrist ganglia are benign soft-tissue tumours of controversial pathogenesis. Most of them are asymptomatic besides swelling but may be associated with pain, interference with activities and an increase in size. Non-surgical management options are not much effective, and surgical excision may invite complications as well as longer recovery period. Homoeopathic treatment remains a very effective measure, but the documentation of it is not adequate. This protocol is designed to evaluate the effect of individualised homoeopathic medicines in cases of wrist ganglion. **Materials and Methods:** The study will be a prospective, parallel arm, randomised, double-blind, placebo-controlled trial. Participants ( $n = 154$ ) will be allocated to individualised homoeopathic medicine group or placebo group by block randomisation. Enrolment will be done for 6 months, and every enrolled participant will be followed up for 8 months. Primary outcome measure will be changes in ganglion size at 8<sup>th</sup> month. Secondary outcome measures will be changes in pain visual analog scale score and patient-rated wrist evaluation score at every month till 8<sup>th</sup> month. **Discussion:** The study may help in generating evidences which may be helpful to validate the effectiveness of individualised homoeopathic medicine in the wrist ganglion.

**Keywords:** Individualised Homoeopathy, Randomised placebo-controlled trial, Research protocol, Wrist ganglion

## INTRODUCTION

Ganglion (M 67.4 as per ICD-10) is benign soft-tissue tumour of joint or tendon (sheath), most commonly encountered in the wrist, but may occur in any joint.<sup>[1]</sup> Sixty per cent to 70% of ganglia are found in dorsal aspect of the wrist.<sup>[2]</sup> The pathogenesis of ganglion remains controversial even today,<sup>[3,4]</sup> though a history of trauma is elicited in at least 10% of cases and is considered as a causative factor.<sup>[1]</sup> It can affect any age group but more common in 20s to 40s.<sup>[1]</sup> Incidence in males and females is 25 and 43 per 1,00,000, respectively. Prevalence is 19% in patients reporting wrist pain and 51% in the asymptomatic population.<sup>[5]</sup> The clinical presentation is usually adequate for diagnosis, except in the cases of ‘occult wrist ganglion’, where MRI and ultrasound are needed to make a diagnosis.<sup>[6]</sup>

Most of the ganglia are asymptomatic besides swelling. In many studies, it was revealed that majority of patients sought advice and treatment because of the cosmetic reason or they were concerned that the growth was malignant.<sup>[6]</sup> Patients usually seek treatment when it is associated with

pain, weakness, interference with activities and an increase in size.<sup>[7]</sup> Conventionally, there are three general treatment approaches: observation, aspiration and surgical excision.<sup>[8]</sup> The non-surgical management options are not much effective, and surgical excision has higher rates of complications and longer recovery period.<sup>[2]</sup>

Patients usually opt for homoeopathic treatment either directly or due to the fear of surgical interventions when being advised for surgery. Traditionally, homoeopathic treatment remains a very effective measure for managing the cases of wrist ganglion, but the documentation of such success stories is not adequate.

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**Received:** 10.01.2018; **Accepted:** 20.05.2019

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**How to cite this article:** Central Council for Research in Homoeopathy. Protocol for efficacy of individualised homoeopathic medicine in cases of wrist ganglion: A prospective, parallel arm, randomised, double-blind, placebo-controlled trial. *Indian J Res Homoeopathy* 2019;13:118-24.

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**DOI:**  
10.4103/ijrh.ijrh\_3\_18

To explore the relevant publications regarding treatment of wrist ganglion by homoeopathic medicines, electronic databases such as MEDLINE,<sup>[9]</sup> PubMed,<sup>[10]</sup> CORE-Hom database<sup>[11]</sup> and AYUSH Research Portal<sup>[12]</sup> were searched with the key words 'ganglion', 'wrist', 'treatment' and 'Homoeopathy'. However, no such publication was found in those electronic databases.

After considering all the available information, it was perceived that documentation of the effect of homoeopathic treatment in cases of wrist ganglion is needed, and a randomised placebo-controlled trial (RCT) is necessary to validate the effectiveness of individualised homoeopathic medicines in wrist ganglion. To serve this purpose, a prospective, parallel arm, randomised, double-blind, placebo-controlled trial will be conducted to find whether there is any statistically significant difference between the outcome of treatment of wrist ganglion by individualised homoeopathic medicine and placebo.

In this RCT, 'placebo' will be used for the comparator group. In different studies, it was seen that the spontaneous resolution rate of untreated ganglion ranged between 42% and 58% within a time period of 3–10 years.<sup>[13,14]</sup> Hence, placebo can be safely used as a comparator, and to minimise the chance of spontaneous resolution, the study duration will be of 8 months only.

This study protocol has been prepared in compliance with Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines<sup>[15]</sup> and NIH-FDA Clinical Trial Protocol.<sup>[16]</sup> The clinical trial will be conducted in compliance with the Declaration of Helsinki<sup>[17]</sup> and Ethical Guidelines for Biomedical Research on Human Participants by ICMR.<sup>[18]</sup>

## STUDY HYPOTHESIS

Null hypothesis ( $H_0$ ) = There is no statistically significant difference between the outcome of treatment of wrist ganglion by individualised homoeopathic medicine and placebo.

Alternative hypothesis ( $H_A$ ) = There is a statistically significant difference between the outcome of treatment of wrist ganglion by individualised homoeopathic medicine and placebo.

## STUDY OBJECTIVES

Primary objective of the study is to evaluate the changes in size of wrist ganglion after completion of 8-month follow-up, both clinically (by measuring scale) and by ultrasonography (USG). Secondary objectives are to evaluate the changes in pain visual analogue scale (VAS) score<sup>[19]</sup> and changes in patient-rated wrist evaluation (PRWE) score<sup>[20]</sup> every month from the baseline till 8<sup>th</sup>-month follow-up.

## TRIAL DESIGN

### Study duration

Enrolment will be done for 6 months, and every enrolled

participant will be followed up for 8 months. Two months will be required for data compilation, data analysis and manuscript writing.

### End of the study definition

A participant will be considered to have completed the study when he/she will complete the follow-up of 8 months and will undergo the final required investigation. End of study shall be considered when last participants' 8th-month follow-up including the required investigation gets completed.

### Study Setting

This study is proposed to be conducted at 'Research OPD' of 'Clinical Research Unit for Homoeopathy, Siliguri' under Central Council for Research in Homoeopathy.

## TRIAL REGISTRATION

The trial has been registered in 'Clinical Trial Registry-India (CTRI)' no. (CTRI/2018/09/015797, registered on 20<sup>th</sup> September, 2018).

## ELIGIBILITY CRITERIA

### Inclusion criteria

Patients of either gender who are aged 18 years or above and having wrist ganglion (diagnosed clinically and by USG) for the duration of 3 months or less will be included in the study provided they are willing to give informed consent to participate in the study. Patients must not be under any kind of treatment for wrist ganglion at least for last 1 month, in such cases washout period will be allowed for 1 month from the last date of intake of previous medicine.

### Exclusion criteria

Patients who are unwilling to give informed consent and/or immunocompromised and/or suffering from critical illness and/or severely drug/alcohol addicted will be excluded from the study.

## INTERVENTION

### Intervention for each group [Figure 1]

Participants who are assigned to 'Active Intervention' group will be given individualised homoeopathic medicine. Selection, potency, dose and repetition of medicine will be as per homoeopathic principles. 'Control intervention' group will receive placebo which will be indistinguishable in appearance from the medicine.

### Follow-up action

After the first prescription, participants will be evaluated by clinical assessment, VAS score and PRWE score at every follow-up. Response to the first prescription (no changes, aggravation or amelioration) will be assessed, and further treatment will be continued as per standard homoeopathic guidelines.<sup>[21]</sup>

### Criteria for discontinuation/modification of allocated intervention

Patients developing extensive pain/distress during the period of study, serious adverse drug events, non-compliance to intervention, unwilling to participate further or with any other issue as per the discretion of investigator shall be withdrawn from the study.

### Intervention adherence

All the participants will be motivated to adhere to the instructions provided by the investigator. They will be also motivated to undergo investigations as per the direction of the investigator.

### Lost to follow-up

A participant will be considered as 'lost to follow-up' if he/she fails to return for two consecutive scheduled visits and is unable to be contacted by the study site investigator.

The study investigator will attempt to contact the participant and reschedule the missed visit. Before a participant is declared as 'lost to follow-up', the investigator will make every effort to regain contact with the participant (where possible, by three telephone calls), and if the participant continues to be unreachable, he/she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

### Concomitant care

Any kind of co-intervention (such as any other medicine, aspiration or surgical intervention) and concomitant care (like physiotherapy) during the study that may affect trial outcomes is to be strictly prohibited.

## OUTCOMES

### Primary outcome measures

Primary outcome measure will be change in size of wrist ganglion which will be measured using measuring scale in three dimensions (length, breadth and height) and also by USG at the end of 8<sup>th</sup> month follow-up.

### Secondary outcome measures

Secondary outcome measures will be change in VAS score and PRWE score which will be determined at every month from the baseline till the end of 8<sup>th</sup> month follow-up.

## SAMPLE SIZE

The sample size calculation was based on the primary objective/outcome of the study as well as on the statistical test used for it.

G\*Power 3<sup>[22]</sup> statistical software was used for this purpose, and the following data were provided in it: statistical test for primary outcome will be two-tailed unpaired *t*-test; effect size was 0.5 (as no such study conducted in past; moderate effect size has been taken);  $\alpha$  was 0.05; Power [P] = (1- $\beta$ ) was 0.8 and allocation ratio was 1:1. Calculated sample size was 128 (64 participants in each group). Anticipating dropout

rate of 20%, the final sample size was 154 (77 participants in each group).

## RECRUITMENT

### Strategies

Patients will be recruited from general outpatient department at the study site. Definite strategies will be adopted for achieving adequate participant enrolment to reach the target sample size. Advertisement about this research project may be done by display of banners containing specific date, place and eligibility criteria to increase awareness about the project.

### Non-achievement of sample size at the centre

In case of non-achievement of sample size in the study period, there will be an option for extension of the study for further limited period after due approval of SAB of the Council. If the study centre fails to achieve the sample size or not complying with the protocol, the study will be discontinued.

## ALLOCATION

### Method of generation of allocation sequence

Allocation sequence will be generated in 1:1 allocation ratio by block randomisation technique with the aid of a computerised random number generator.

### Allocation concealment

Allocation sequence of the participants will be concealed until the 8<sup>th</sup>-month follow-up of all the participants will be completed and the database has been locked. The sealed randomisation list will be stored by the principal investigator (PI).

### Allocation implementation

Randomisation, blinding and allocation sequence generation will be done by PI. Enrolment of the participants will be done by the investigators at the study site

## BLINDING (MASKING)

The study will be a double-blind study, where the trial participants (patients) and the care providers (treating physician/investigator) at the study site will be kept blinded about the allocation of participants in the treatment and placebo groups.

Emergency unblinding may be done only in exceptional circumstances when knowledge of the actual treatment provided is very much essential for further management.

## DATA COLLECTION PROCEDURE

Screening will be done using pre-designed 'Screening Form'. Eligible patients will be provided 'Participant Information Sheet' (in local language) detailing about the study protocol, risks and benefits of participation. Voluntary 'Written Informed Consent' will be taken from the patient before he/she is enrolled

in the study. Pre-designed ‘Case Recording Format’ (CRF) will be used for baseline assessment. Pharmacist will dispense the prescribed medicine/placebo to the patient as per the randomisation chart. Patients will be followed up every month for the period of 8 months as per ‘Follow-up Sheets’. Any adverse events (AEs) must be recorded in ‘Adverse event recording pro forma’. At the end of 8<sup>th</sup>-month follow-up, the investigator at the study site will fill up the ‘Case-off study form’ with detailed information regarding relevant events of each case in chronological order.

### DATA MANAGEMENT

Pre-designed ‘CRF’ and ‘Follow-up Sheets’ will be used for collection of data in hard format which will be transferred to a pre-designed spreadsheet. Study site will remain responsible for storage and security of all data as well as for the completeness and accuracy of the study records. Participant files will be maintained in storage for a period of 5 years after the publication of the study report.

### STATISTICAL METHODS

Appropriate statistical methods will be utilised for analysis of primary and secondary outcomes as per ‘intention-to-treat’ approach. Statistical software (e.g., SPSS, IBM SPSS Statistics for Windows, 2017; Version 25.0. Armonk, NY, IBM Corp.) may be used for statistical analysis. ‘Non-parametric tests’ will be used for categorical (nominal/ordinal) data, and ‘parametric tests’ will be used for quantitative (continuous/discrete) data.

### MONITORING

This study will be monitored regularly by PI at the study site.

### RECORDING OF ADVERSE EVENTS

‘Any untoward medical occurrence in a subject without regard to the possibility of a causal relationship’ will be recorded as an ‘AE’ and will be managed by the study investigator either by homoeopathic treatment or by referring to an appropriate facility.

‘Any untoward medical occurrence that is believed by the investigators to be causally related to the study drug and results in any of the following: life-threatening condition (that is, immediate risk of death), severe or permanent disability, prolonged hospitalisation or a significant hazard as determined by the data safety monitoring board’ will be considered as ‘Serious Adverse Events’ and in such cases, relation of an event to the study drug based on a temporal relationship to the study drug, as well as whether the event is unexpected or unexplained given the patient’s clinical course, previous medical conditions and concomitant medications will be investigated.

### AUDITING

Auditing will be conducted by the PI at the study site on

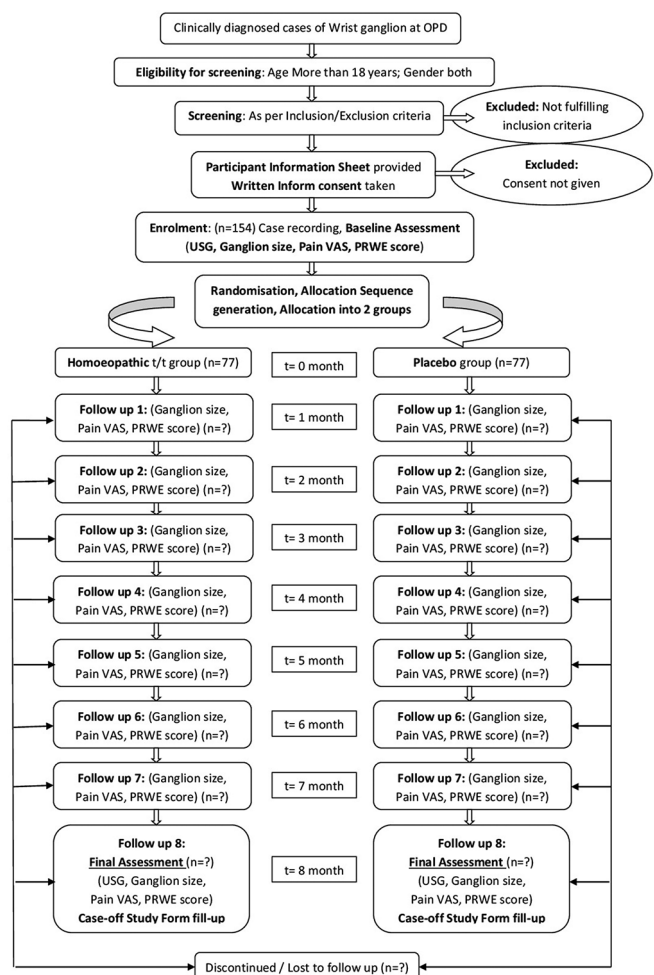


Figure 1: Participant flow diagram

monthly basis. It will involve periodic independent review of participant enrolment, consent, eligibility, allocation to two groups, adherence to trial interventions, completeness and accuracy of data collection. It will also be reviewed that whether the study is conducted in accordance with the Declaration of Helsinki and Ethical Guidelines for Biomedical Research on Human Participants by ICMR.

### ETHICAL CONSIDERATIONS

The study protocol is in compliance with the Declaration of Helsinki<sup>[17]</sup> and Ethical Guidelines for Biomedical Research on Human Participants by ICMR.<sup>[18]</sup> Necessary ethical approval has been obtained from the ‘Institutional ethics Committee’ of the study site on 4<sup>th</sup> August 2018.

### PROTOCOL AMENDMENTS

Any significant changes required to be done in study objectives, study design, sample size or study procedures have to be approved by the Institutional Ethics Committee of the study site. Minor administrative or technical amendments which do not affect the way of study, may be done after agreement of all those concerned.

## Consent

The investigators of the study site will introduce the study procedure to the participants. Every participant will receive the 'Participant Information Sheet'. The investigator will obtain 'written consent' from the patients willing to participate in the trial.

## Confidentiality

All information collected in this study will be kept strictly confidential. The privacy and confidentiality will be honoured, and identifying information pertaining to any patient shall be coded and not disclosed at the time of publication/presentation of the study results.

## STATEMENT OF COMPLIANCE

The study will be reported as per 'Consolidated Standards of Reporting Trials'<sup>[23]</sup> guidelines and its supplement 'Reporting data on homeopathic treatments (RedHot)'.<sup>[24]</sup>

## ACCESS TO DATA

The complete final database will be accessed by the PI.

## POST-STUDY CARE

The patients will be followed up even after completion of the study period if required.

## PUBLICATION AND AUTHORSHIP POLICY

Council will reserve the authority to publish original articles based on the primary and secondary outcomes emerging from the study. The names of the contributors who have made substantial intellectual contributions in the study will be considered for authorship of manuscript as per guidelines provided by the International Committee of Medical Journal Editors.<sup>[25]</sup>

## Acknowledgement

The authors deeply acknowledge Dr. Anil Khurana, DDG (CCRH), Dr. Praveen Oberai, RO(H), S-4, Dr. V. Roja, RO (H)/S-2, Dr. Kalpana Gautam, SRF(H), CCRH for technical support.

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## Financial support and sponsorship

The study was funded by Ministry of AYUSH, Government of India.

## Conflicts of interest

None declared.

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### रिस्ट गैंगलिओन के मामलों में व्यक्तिगत होम्योपैथिक दवा की प्रभावशीलता: एक संभावित, समानांतर, यादृच्छिक, डबल ब्लाइंड, प्लेसिबो नियंत्रित परीक्षण

**पृष्ठभूमि और उद्देश्य:** कलाई गैंगलिओन विवादास्पद रोगजनन के सौम्य नरम ऊतक ट्यूमर हैं। उनमें से ज्यादातर सूजन के अलावा स्पर्शोन्मुख हैं लेकिन दर्द, गतिविधियों के साथ हस्तक्षेप और आकार में वृद्धि के साथ जुड़ा हो सकते हैं। गैर-सर्जिकल प्रबंधन विकल्प अधिक प्रभावी नहीं हैं और सर्जिकल छांटना जटिलताओं और साथ ही साथ लंबी अवधि को भी आमंत्रित कर सकता है। होम्योपैथिक उपचार एक बहुत प्रभावी उपाय है, लेकिन इसका प्रलेखन पर्याप्त नहीं है। यह प्रोटोकॉल कलाई गैंगलिओन के मामलों में व्यक्तिगत होम्योपैथिक दवाओं के प्रभाव का मूल्यांकन करने के लिए बनाया गया है।

**सामग्री और विधि:** अध्ययन एक संभावित, समानांतर आर्म, यादृच्छिक, डबल ब्लाइंड, प्लेसिबो-नियंत्रित परीक्षण होगा। प्रतिभागियों (एन = 154) को ब्लॉक रैंडमाइजेशन द्वारा व्यक्तिगत होम्योपैथिक दवा समूह या प्लेसिबो समूह को आवंटित किया जाएगा। फॉलोअप की अवधि आठ महीने होगी। आठवें महीने में गैंगलिओन आकार में प्राथमिक परिणाम माप में बदलाव होंगे। माध्यमिक परिणाम उपाय दर्द वीएस स्कोर और पीआरडब्ल्यू स्कोर में हर महीने आठवें महीने तक बदलाव होंगे।

**विचार-विमर्श:** अध्ययन उन सबूतों को उत्पन्न करने में मदद कर सकता है जो गैंगलिओन में व्यक्तिगत होम्योपैथिक दवा की प्रभावशीलता को मान्य करने में सहायक हो सकते हैं।

### Efficacité des médicaments homéopathiques personnalisés dans le traitement des ganglions au poignet : une étude prospective, randomisée, à double insu et bras parallèles et contrôlée par placebo.

**Contexte et Objectifs:** Les ganglions au poignet sont des tumeurs bénignes de tissus mous et ont une pathogénie controversée. La plupart de ces ganglions sont asymptomatiques, à part le gonflement, mais peuvent être accompagnés de douleur, associés à une augmentation de la taille et nuire aux activités. Les options non chirurgicales ne sont pas très efficaces et une excision chirurgicale pourrait non seulement mener à des complications mais également prolonger la période de convalescence. Le traitement homéopathique reste une mesure très efficace mais sa documentation n'est pas suffisante. Cette étude a comme objectif d'évaluer l'effet des médicaments homéopathiques individualisés en cas de ganglions au poignet.

**Matériels et Méthodes:** L'étude sera prospective, randomisée, à double insu et bras parallèles et contrôlée par placebo. Les participants ( $n = 154$ ) seront répartis en 2 groupes, le groupe recevant le médicament homéopathique individualisé ou le groupe placebo, suivant la technique de randomisation par bloc. La période de suivi sera de huit mois. Le critère principal d'évaluation sera le changement de la taille du ganglion au bout de huit mois. Les critères secondaires d'évaluation seront les changements des scores de douleur, selon l'EVA (Échelle visuelle analogique) et selon l'Évaluation du poignet par le patient (EPP), observés mensuellement et ce jusqu'au huitième mois.

**Discussion:** L'étude peut aider à obtenir les preuves qui pourraient s'avérer utiles pour valider l'efficacité des médicaments homéopathiques personnalisés dans le traitement du ganglion au poignet.

### **Eficacia del medicamento homeopático individualizado en casos de quistes ganglionares de muñeca. Ensayo prospectivo, de brazo paralelo, a doble ciego y controlado con placebo**

**Fundamentos y Objetivos:** Los quistes ganglionares de muñeca son tumores benignos de tejidos blandos de patogénesis controvertida. La mayoría de ellos son asintomáticos aparte de provocar hinchazón, aunque pueden asociarse a dolor, interferencias en la actividad y un aumento del tamaño. Las opciones de tratamiento no quirúrgico no son muy efectivas y la escisión quirúrgica puede provocar complicaciones y un período de recuperación más prolongado. El tratamiento homeopático sigue constituyendo una medida muy eficaz, pero no se dispone de la documentación adecuada. Este protocolo se ha diseñado para evaluar el efecto de los medicamentos homeopáticos individualizados en casos con quistes ganglionares de muñeca.

**Materiales y Métodos:** El estudio será un ensayo prospectivo, de brazo paralelo, aleatorizado a doble ciego y controlado con placebo. Los participantes ( $n = 154$ ) se asignarán al grupo con el medicamento homeopático individualizado o al grupo de placebo mediante aleatorización en bloque. El periodo de seguimiento será de ocho meses. Los parámetros primarios serán los cambios en el tamaño del quiste ganglionar a los 8 meses. Los parámetros secundarios serán los cambios en la puntuación VAS del dolor y la puntuación PRWE cada mes a los 8 meses.

**Discusión:** El estudio puede ayudar a generar evidencias útiles para validar la eficacia del medicamento homeopático individualizado en los quistes ganglionares de muñeca.

### **Wirksamkeit der individualisierten homöopathischen Behandlung bei Ganglien am Handgelenk: Eine prospektive, randomisierte, doppelblinde, placebokontrollierte Parallelarmstudie**

**Hintergrund:** Ganglien am Handgelenk sind gutartige Weichteiltumoren mit einer unterschiedlichen Pathogenese. Meistens sind sie, abgesehen von Schwellungen, asymptomatisch. Sie können jedoch bei Aktivitäten mit Schmerzen und Beeinträchtigungen einhergehen, sowie an Größe zunehmen. Nicht-chirurgische Behandlungsoptionen sind sehr uneffektiv und chirurgische Exzisionen können zu Komplikationen und zu einer daraus folgenden notwendigen längeren Erholungsphase führen. Die homöopathische Behandlung bleibt eine sehr wirksame Maßnahme, die jedoch noch nicht ausreichend dokumentiert ist.

**Ziel:** Mit dieser Studie soll die Wirkung von individualisierten homöopathischen Arzneimitteln bei Handgelenksganglien untersucht werden.

**Materialien und Methoden:** Bei der Studie handelt es sich um eine prospektive, randomisierte, doppelblinde, placebokontrollierte Parallel-Armstudie. Die Teilnehmer ( $n = 154$ ) werden durch Block-Randomisierung einer individualisierten homöopathischen Gruppe oder einer Placebo-Gruppe zugeordnet. Die Nachbeobachtungszeit beträgt acht Monate. Das primäre Ergebnis ist die Veränderung der Gangliengröße nach acht Monaten. Sekundäre Ergebnisse sind monatliche Änderungen des „Pain VAS-Scores“ und des „PRWE-Scores“ bis zum achten Monat.

**Diskussion:** Die Studie kann hilfreiche sein, nützliche Nachweise zu erbringen, um die Wirksamkeit individualisierter homöopathischer Arzneimittel beim Handgelenksganglion zu validieren.

### **Effectiveness of individualized homeopathic medicine in cases of wrist ganglion: A prospective, parallel arm, randomized, double blind, placebo controlled trial**

**個人化順勢療法藥物在腕部腱鞘囊腫個案中的有效性：一個前瞻性、平行組、隨機、雙盲、安慰劑對照試驗**

**背景和目標：**腕部腱鞘囊腫是良性軟組織腫瘤，其發病機制存在爭議。除腫脹外，大多數都是無症狀的，但可能會伴隨疼痛、干擾活動和尺寸增加。非手術治療方案效果不太，手術切除可能引起併發症，並且恢復期較長。順勢療法一直是一種非常有效的措施，但其記錄文獻並不充分。本方案旨在評價個人化順勢療法治療腕部腱鞘囊腫的療效。

**材料和方法：**該研究將是一項前瞻性、平行組、隨機、雙盲、安慰劑對照試驗。參與者（ $n = 154$ ）將通過塊狀隨機分派分為使用個人化順勢療法藥物組或安慰劑組。隨後跟進期限為八個月。主要的結果是量度第八個月時其神經節大小的變化。次要結果指標將是每月至第八個月的VAS疼痛評分和PRWE評分的變化。

**討論：**該研究可能有助於產生可能有助驗證腕部腱鞘囊腫中用個人體化順勢療法藥物有效性的證據。