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GangLion Resection Effectiveness Trial (GangLion): a Multicentre, Randomized, Superiority Trial

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Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities

The study authors (LL, TK, JJ, PN, AKSC, AC) planned the study, including its objectives and design, methods for implementation, management, statistical analysis, writing of the protocol. The study authors will take a decision to register the protocol for publications as well as have the final responsibility for the decision to submit study results for publication.

The funder had no role in planning the study, including its objectives and design, methods for implementation, management, statistical analysis, writing of the protocol or the decision to register the protocol for publication.

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ABSTRACT

Background: Wrist ganglions are often referred to as the most common soft tissue tumours of the hand. They are also the most frequently excised hand tumours. However, the optimal treatment for ganglions remains uncertain.

Objective: The aim of the study is to determine whether operative treatment results in better patient-reported outcomes and satisfaction than conservative treatment over a 6-month follow-up period.

Methods: This is a multicentre, randomized, parallel group (1:1), controlled, superiority trial. We will recruit 220 patients in Finland and Singapore. The main inclusion criteria are wrist pain located in the ganglion area and a diagnosis of wrist ganglion based on clinical examination or imaging findings. In the conservative treatment group, participants are advised to use hand as tolerated and are provided with simple, self-administered exercise instructions. In the operative treatment group, the ganglion resection is performed in an operating room using either an arthroscopic or open approach. The primary outcome is Patient-Rated Wrist/Hand Evaluation (PRWHE) pain score at 6 months of follow-up. Secondary outcomes include the PRWHE pain score at other time points, PRWHE total and function scores, self-reported global improvement on a 7-step Likert scale, Patient Accepted Symptom State (PASS), health-related quality of life (measured by the EuroQol visual analogue scale [EQ VAS]), presence of the ganglion, duration of sick leave (in days), and adverse events. Follow-up questionnaires are collected directly via *REDCap* software at 3, 6, and 12 months of follow-up.

Ethics and dissemination: We will obtain approval of the local ethics committee for the protocol and informed consent form. The study will be conducted in accordance with the Declaration of Helsinki. We will publish the protocol and study results in peer-reviewed journals.

INTRODUCTION

Wrist ganglions, benign soft tissue tumour, account for 59% of soft tissue tumours in the hand (1) and are often referred to as the most common soft tissue tumour of the hand (2,3). Reviews suggest that approximately 70% of wrist ganglions are dorsal and 20% volar (2,4) although a magnetic resonance imaging study reported the opposite distribution (5). In a Singaporean cohort, ganglions were found to be twice as common in females as in males (6). Additionally, patients with ligamentous hyperlaxity are at a higher risk of developing symptomatic dorsal ganglions (7).

Clinically ganglions are more likely to be annoying than debilitating. There may be a palpable mass from few millimetres up to several centimetres. Various case series report pain in 41% to 100% of patients before treatment. (8–10) However, ganglions are extremely common within people with asymptomatic wrists. Lowden et al. (5) performed magnetic resonance imaging (MRI) for 103 asymptomatic volunteers aged 36 year-old (range 16 to 67) and 51% had wrist ganglions. We cannot explain why some ganglions are symptomatic while others are not. Compression to superficial branch of the radial nerve has been assumed to be one cause pain (11).

Despite being the most commonly excised hand tumour (6), the optimal treatment for ganglions still remains uncertain. (12). Nonsurgical options including aspiration, NSAIDs, and splinting are typically attempted first, though their effectiveness is unclear. (2,4,12). Surgery is considered for pain, stiffness, cosmetic concerns, or fear of malignancy, with both open and arthroscopic techniques available (2,4). A study by Dias et al. (13) followed 236 patients up to 70 months and found out that symptom resolution was similar irrespective of treatment. These findings, along with the fact that many ganglions are asymptomatic, highlight our limited understanding of its pathophysiology and symptom correlation. (14)

Multiple randomized controlled studies have compared different treatment options in wrist ganglions (15–26), including six studies on different aspiration or puncture methods (15,19,21,22,24,25), four comparing aspiration with surgery (16,18,20,23), and two comparing open vs arthroscopic resection (17,26). Most focused on ganglion recurrence at 12 months as the primary outcome, with limited attention to patient important outcomes; only in two studies (15,17) reported pain, and none assessed patient satisfaction or patient reported outcomes measurements (PROMs).

In 2015, Head et al. (3) conducted a review and meta-analysis of wrist ganglions, including six studies, and reported a 76% reduction in recurrence with operative treatment compared to aspiration alone. More recently, Horvath et al. (27) reviewed 11 studies on dorsal wrist ganglions highlighting significant variability in recurrence rates across aspiration, open resection, and arthroscopic resection. However, no studies have compared operative treatment with conservative care while focusing on patient-centred outcomes, despite surgery often being performed to address wrist pain and disability. Therefore, the aim of our study is to determine whether operative treatment results in better patient-reported outcomes and satisfaction than nonsurgical treatment over a 6-months follow-up period.

Trial design

The trial design is multicentre, randomized, parallel group (1:1) controlled, superiority trial.

METHODS

Study setting

We will recruit patients from national tertiary and secondary referral centres in Finland and in Singapore. To qualify as a study site, the hospital has at least one practicing specialist in hand surgery (lead investigator, LI) who performs the surgeries. All the LIs are required to be board certified hand

surgeons, and they must have resected (open or arthroscopic) at least ten ganglions prior to the study commencement.

Eligibility criteria

The LI will screen all the patients who are referred to the study centres under ganglion diagnosis. The inclusion criteria are (1) wrist pain located in the ganglion area, (2) diagnosis of ganglion of the wrist, based on clinical examination or imaging findings, (3) age over 18 years, and (4) ability to fill out the Finnish or English version of the questionnaires. If there is symptomatic ganglion in both wrists, the more symptomatic is included. The exclusion criteria are (1) pregnant or breast feeding, (2) other known wrist pathology that likely explains the pain, (3) previous surgical treatments of the wrist, and (4) wrist ganglion presumed to be related to a work injury.

Interventions

In the conservative treatment group, participant will be informed about the natural course of wrist ganglions. The conservative treatment may include needle aspiration of the ganglion, but it is not performed routinely. Participants are informed that wrist loading in extension may exacerbate the pain, and that the pain is not a sign of further injury to wrist joint. They can avoid heavy use it if they have too much pain, but they are advised to use hand as tolerated. Participants may use NSAIDs and acetaminophen for pain management as needed; however, the protocol does not specify a required course or dosage. A simple self-implemented exercise therapy instructions are given to every participant (Supplemental material), including those undergoing surgery.

In the operative treatment group, the ganglion resection is performed in an operation room either through arthroscopy or open approach. The method is left to surgeon to decide. In open resection, a transverse or longitudinal incision is done depending on surgeon's preference. The ganglion and its

pedicle are traced up to its origin. The pedicle is resected tangentially, usually, from the SL ligament for dorsal ganglions and depending on the site for volar ganglion. Wrist capsule is not closed. In arthroscopic resection, portals are selected by surgeon's preference. The pedicle of the ganglion is located and resected with a shaver. It is not necessary to remove all the ganglion walls. The portal incisions do not need to be sutured. In both treatment methods, a bulky dressing is applied for patient's comfort and removed within a week. Active range of motion exercises are begun immediately.

Study variables

Study variables and follow-up time points are summarized in Table 1.

Table 1. Study variables and participant timeline.

	Enrolment	**Follow-up**		
Timepoint	Baseline	3 months	6 months	12 months
Enrolment				
Eligibility screen	X			
Informed consent	X			
Randomization	X			
Assessments				
Outpatient visit	X		X	
Baseline data	X			
PRWHE total	X	X	X	X
PRWHE function	X	X	X	X
PRWHE pain	X	X	X	X
Global improvement		X	X	X
PASS		X	X	X
EQ VAS	X	X	X	X
Presence of ganglion			X	
Sick leave, days	X		X	
Adverse events		X	X	X

PRWHE, Patient-Rated Wrist/Hand Evaluation; PASS, Patient Acceptable Symptom State; EQ VAS, EuroQol visual analogue scale

Primary outcome of the trial is Patient-Rated Wrist/Hand Evaluation (PRWHE) pain score at 6 months of follow-up (Table 1).

Secondary outcomes are: PRWHE pain score at other time points, PRWHE total and function scores, self-reported global improvement on a 7-step Likert scale, Patient Accepted Symptom State (PASS), health-related quality of life (measured by EuroQol visual analogue scale, EQ VAS), presence of the ganglion, duration of sick leave (in days), and adverse events.

The PRWHE is a 15-item questionnaire that is designed to measure wrist pain and disability in activities of daily living. Symptoms are described as average over the past week. The PRWHE consists of two subscales: pain and function. The PRWHE pain includes five items with combined score from 0 (no pain) to 50 (worst ever). The PRWHE function includes ten items that are further divided in specific activities (six items) and usual activities (four items). Score of the PRWHE function ranges from 0 (no difficulty) to 50 (unable to do). The PRWHE total ranges from 0 (best) to 100 (worst). (28) The minimal clinically important difference (MCID) for the PRWHE total, pain, and function scores have been estimated to be between 16 and 20, 9 and 11, and 9 and 10, respectively (29).

Self-reported global improvement will be gathered as 7-step Likert scale as a response to question: “Compared with the beginning of the study, my wrist feels much worse – somewhat worse – little worse – no change – little better – somewhat better – much better.”

PASS will be assessed using the question: “Considering the current symptoms and function of your wrist, are you satisfied with the outcome?” Participants will respond with either 'yes' or 'no'.

EQ VAS is a component of 5-level EQ-5D questionnaire. It measures patient’s overall current health-related quality of life in a 20 cm visual analogue scale. The scale ranges from 100 (“the best health

state you can imagine") to 0 ("the worst health you can imagine"). MCID is baseline-dependent and varies between 2.8 and 13.2 (30).

The presence of the ganglion will be assessed through clinical examination at the 6-month follow-up. The duration of sick leave will be reported by participants at the 6-month follow-up.

Participant timeline

The time schedule for enrolment and visits is presented in Table 1.

General practitioners (GPs) refer patients to study sites for consideration of surgical treatment. The patients with suspected ganglion of the wrist are directed to an outpatient clinic, where the LI screens potentially eligible patients.

After confirming eligibility, the LI will inform patients about the trial. All patients will receive a written information about the trial. Patients will be provided with all the relevant study information: objectives, duration and timelines, advantages or disadvantages of participation, rights of discontinuing the study, importance of adhering to the allocated interventions, and study protocol instructions. If the patient consents for the study, they will undergo the baseline assessment. The baseline data is saved to the web application *REDCap* that is secure web-based application for online surveys and databases (31,32). After the baseline data is saved, the application allows randomization.

After allocation, surgery is scheduled, or the investigator, study site research nurse, or physiotherapist provides the information for the conservative treatment group.

The follow-up questionnaires including PRWHE, self-reported global improvement, PASS, EQ VAS, presence of the ganglion, sick leave, and adverse events are collected directly to electronical database. For data collection and storage, we use *REDCap* software which allows participants to fill in the questionnaires with phone or computer at home. The outcomes are collected at 3, 6, and 12 months after randomization. Participants are invited to the outpatient clinic at 6 months where the ganglion presence is evaluated.

The participant is instructed not to have other treatments before the 6 months of follow-up. In the conservative treatment group, the treatment options are discussed at the outpatient clinic at 6 months if there are recurrent symptoms.

Sample Size

A typical SD has been reported to be 12 for the PRWHE pain (33), and estimated minimal clinically important difference (MCID) has been reported as 9 points (29). We calculated the sample size using slightly stricter assumptions since the SD has varied between the studies: SD of 15 and a mean difference of 6 points between the groups. Based on these assumptions, the required sample size is 98 per group (196 participants in total). To allow for a 10% loss, we will recruit 220 participants for this study.

Strategies to Improve Adherence

We expect high adherence to the treatment in surgery group since surgery is delivered soon after recruitment and is a one-time treatment. To improve the adherence in conservatively treated controls, we rely on informing participants well before the study, and we will explain that a short follow-up of 6 months is safe and will cause no further damage in their wrists. We will also let the participants in the conservative treatment group to switch to operative treatment after the six months follow-up if

they wish so due to difficult symptoms. To improve response rate, we will send a link to questionnaires to each participant and remind them if they have not responded within seven days. If they still do not fill in the questionnaires, we will offer opportunity to respond to the questionnaires in a phone call. Patients can quit the trial whenever they want and only the collected data will be used in the trial.

Sequence generation and allocation concealment

We will use a centralized randomization system with built in random sequence generation and allocation concealment. A person not involved in recruitment will generate the random sequence list and upload it to *REDCap*. The *REDcap* will not allow investigators to see the allocation sequence. After the participant has given the informed consent and the investigator has saved the baseline data, the software will release the allocation code. The participants are allocated 1:1 with a random block size. The location of the ganglion (dorsal/volar) and study country (Finland/Singapore) will be used as stratification criteria

Blinding

Due to the nature of the interventions and inability to blind the participants with placebo surgery (as the visible mass would reveal the allocation after surgery), blinding is not possible. Since the outcomes are participant reported, we will not attempt to blind the investigator or other personnel.

We will use blinded data interpretation as described before (34).

Data collection and management

Baseline data includes age, sex, handedness, history of smoking, history of diseases or usual use of medicine, occupation, history of ganglion treatment, and outcome measures.

Each participant in the trial will receive a unique trial identification number (TIN), which will be linked to their personal identification number (ID). This number will be assigned once the participant has provided informed consent. TINs will be issued in sequential order and will not be reused. Throughout the study, all research data will be managed using these TINs.

Both primary and secondary outcomes will be collected and managed using *REDCap* electronic data capture tools hosted at a secure server either in Pirkanmaa Wellbeing County (Finland) and in National University Hospital (Singapore), depending on the country of the study site (31,32). *REDCap* (Research Electronic Data Capture) is a secure, web-based software platform designed to support data capture for research studies, providing 1) an intuitive interface for validated data capture; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for data integration and interoperability with external sources. Participants will enter data during their initial visit using a tablet. For the follow-up visits, the participants will receive a link to the questionnaires via email or text message as per their preference. Patient-reported outcomes will be directly recorded into the *REDCap* system, with mandatory fields enabled to prevent incomplete submissions. Investigators from all participating hospitals will have access to the data from their own centre. Once the study is complete, the pseudonymized data from Singapore is merged to the pseudonymized data in Finland and the study statistician will perform planned analyses. All investigators will have access to the aggregate level data.

Statistical plan

We will perform all primary analyses on the intention-to-treat principle. Per protocol and as treated analyses will be performed as sensitivity analyses if the adherence is under 90% in either group. We

will present descriptive statistics as means with SDs, as medians with IQR, or as counts with percentages as appropriate.

A repeated measures mixed model (RMMM) will be used to compare the group means. The hierarchical model will include treatment, ganglion site, and treatment*time point interaction as fixed factor and participant (nested within the study site) and study site as random factors. The baseline value is entered into model as covariate for all continuous outcomes. We will interpret the untransformed coefficient (for treatment group) as treatment effect and report it with 95% confidence intervals. For self-reported global improvement, we will use ordinal logistic model (if the proportional odds assumption holds) or binary logistic model. For PASS, we will use binary logistic model.

Data monitoring

This study will be carried out without the external monitoring committee. Clinical research coordinator in each centre will regularly check the data for inconsistencies. Outlier values will be identified during the data checking and values confirmed from the centres.

Harms

We will inquire about any adverse events via *REDCap* at 3, 6, and 12 months after randomization. The prespecified and systematically assessed harms include infection, nerve or tendon injury, complex regional pain syndrome (CRPS), and restricted range of motion in the fingers. Infection, nerve injury (dysesthesia or paresthesia at the innervation area), and tendon injury (inability to move finger or wrist due to injury) are diagnosed clinically. Diagnosis of CRPS is based on the Budapest criteria (35). These harms can be diagnosed at any level of the healthcare system. Restricted range of motion in the fingers is evaluated as the inability to touch the palm with the fingers. Unlike the other

harms, it is assessed during the appointment at 6 months after randomization. For non-prespecified harms, a free-text field is included in *REDCap* questionnaire.

An adverse event is a serious adverse event (SAE) when it requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, is life-threatening, or results in death.

Auditing

No auditing will take place between the participating centres during the trial.

ETHICS AND DISSEMINATION

Research ethics approval

The study protocol will be registered with clinicaltrials.gov. This protocol was written according to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement (36). We will acquire approval of the local ethics committee for the protocol and informed consent form. This study will be conducted in accordance with the Declaration of Helsinki.

Protocol amendments

We will acquire approval of the institutional review board before implementation of the amendments. If there are any protocol amendments, LIs are informed. We will also report possible amendments in the clinicaltrials.gov registry.

Consent

The LI will inform patients about the trial at the first appointment. All patients will receive written information about the trial. Patients will be provided with all the relevant study information:

objectives, duration and timelines, potential benefits and risks of participation, the right to discontinue participation at any time, the importance of adhering to the allocated interventions, and study protocol instructions.

If consideration period is needed, the patient will have opportunity to contact the LI afterward. The LI will obtain written informed consent form the patients who are willing to participate in the trial. The consent form is provided in Finnish (in Finland) and English (in Singapore) and is available in the supplemental material.

Participation in the trial is voluntary, and the patient can withdraw the consent at any time without providing a reason. If a patient refuses or discontinues the trial, standard care will be provided as usual.

Confidentiality

The data will be stored in a password-protected database operated via the *REDCap* platform (https://www.project-redcap.org/) that is hosted on a secure server at Pirkanmaa Wellbeing County (Finland) and at National University Hospital (Singapore). All data will be retained for fifteen years following the conclusion of the trial.

Declaration of interests

Nothing to declare.

Access to data

Access to the study database will be restricted to authorized trial researchers. The stored data will consist solely of pseudonymous TINs and numerical responses from questionnaires. This ensures that the participants' identities remain confidential.

Ancillary and post-trial care

In the conservative treatment group, the participants may receive surgery also after the study has finished. For other hand symptoms, participants can contact their local health centre or own GP.

Dissemination policy

We will publish the protocol and results in peer-reviewed journals. Members of the steering committee and writing committee, and LIs from each centre are eligible for authorship of the publications. The principal investigators (LL, TK, PN, AKSC) will designate the writing committee, which will be responsible for reporting the data. On request and if current legislation allows, we will provide the anonymized data of the study to be available but not before the study conclusion. Funding bodies do not access to data and are not allowed to participate in decisions regarding publications.

DISCUSSION

Previous studies on wrist ganglions have primarily focused recurrence rates, despite many ganglions being asymptomatic. Recurrence alone does not reflect treatment benefits in patient-important outcomes like pain and disability. This study aims to compare surgery and conservative treatment, emphasizing patient-important outcomes.

Wrist ganglions are common in young, working-age individuals and can cause symptoms that impact work and hobbies. However, surgical treatment may also result in time away from work or reduced participation in hobbies, and it remains unclear whether surgery improves these aspects.

The study has some limitations. The follow-up period is relatively short, but this minimises the risk of dropout, and significant improvement beyond six months is unlikely. Additionally, neither participants nor treating physicians are blinded, introducing potential performance and detection bias. However, due to the nature of the interventions, blinding participants is not feasible. Previous meta-analyses suggest that the impact of this lack of blinding is generally small (37).

In summary, this study aims to identify the most effective treatment for a common wrist condition, with the potential to influence current practices. While symptomatic wrist ganglions are often treated surgically, there is limited evidence that surgery improves functional capacity.

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