ISRCTN71616121 https://doi.org/10.1186/ISRCTN71616121

# Cold spray before local anaesthetic injection reduces pain in patients undergoing percutaneous needle aponeurotomy for Dupuytren's disease

**Submission date**
20/08/2025

**Recruitment status**
No longer recruiting

**Registration date**
18/09/2025

**Overall study status**
Completed

**Last Edited**
20/08/2025

**Condition category**
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

## Plain English summary of protocol

Background and study aims
Dupuytren's disease is a condition that causes the fingers to curl towards the palm due to thickening of tissue in the hand. A minor surgical procedure called percutaneous needle aponeurotomy is commonly used to treat this condition. The procedure is performed under local anaesthetic, but the injection of anaesthetic into the palm can be painful. This study aims to test whether applying a cooling spray (vapocoolant) before the injection can reduce pain compared to anaesthetic alone.

Who can participate?
Adults aged 18 years or older with Dupuytren's disease in one hand who are scheduled for percutaneous needle aponeurotomy (PNA) can take part. People with an allergy to local anaesthetic, nerve damage in the affected hand, or difficulty providing informed consent are not eligible.

What does the study involve?
Participants are randomly assigned to one of two groups. One group will receive a 5-second application of cooling spray to the palm before the local anaesthetic injection, while the other group will receive the injection without spray. The injection technique is otherwise identical for both groups. Participants will be asked to rate their pain on a 10-point scale immediately after the first injection. Any side effects will also be recorded.

What are the possible benefits and risks of participating?
The possible benefit is reduced pain from the injection if the cooling spray is effective. There are no known serious risks from the spray when used briefly on intact skin. Both groups will receive standard anaesthesia and the procedure will be carried out as usual, so there is no risk of reduced treatment effectiveness.

Where is the study run from?
Peninsula Health (Australia)

When is the study starting and how long is it expected to run for?
July 2024 to July 2026

Who is funding the study?
Peninsula Health (Australia)

Who is the main contact?
Dr Ishith Seth, Ishithseth1@gmail.com

# Contact information

### Type(s)
Public, Scientific, Principal investigator

### Contact name
Dr Ishith Seth

### ORCID ID
https://orcid.org/0000-0001-5444-8925

### Contact details
2 Hastings Road
Melbourne
Australia
3199
+61 (0)397847777
ishithseth1@gmail.com

# Additional identifiers

### Protocol serial number
Institutional ethics approval reference: QA/112967/PH-2024-450358(v1)

# Study information

### Scientific Title
Adults undergoing percutaneous needle aponeurotomy for Dupuytren’s disease randomised to vapocoolant spray prior to local anaesthetic infiltration versus no spray: a single-centre, single-blind randomised controlled trial measuring injection pain

### Study objectives
Primary objective:
To determine whether vapocoolant spray applied immediately before local anaesthetic infiltration reduces injection pain during percutaneous needle aponeurotomy (PNA) for Dupuytren’s disease.

Hypothesis:
Vapocoolant spray reduces injection pain compared with lignocaine infiltration alone, achieving a clinically and statistically significant reduction in VAS pain score.

Secondary objectives:
1. Assess immediate adverse events or perioperative complications.
2. Explore correlations between injection pain and demographic or disease-related factors (age, sex, Tubiana grade).

## Ethics approval required
Ethics approval required

## Ethics approval(s)
Approved 20/09/2024, Peninsula Health (2 Hastings Road, Frankston, Melbourne, 3199, Australia; +61 (0)397847777; customer.relations@phcn.vic.gov.au), ref: QA/112967/PH-2024-450358(v1)

## Primary study design
Interventional

## Study design
Single-centre single-blind parallel-group randomized controlled interventional trial

## Study type(s)
Treatment, Safety, Efficacy

## Health condition(s) or problem(s) studied
Dupuytren’s disease

## Interventions
Vapocoolant spray group:
Application of commercially available menthol-based vapocoolant spray (Mentholatum Ice Spray, Australia) for 5 seconds at a distance of 10 cm to the injection site, immediately prior to infiltration with 1% plain lignocaine (4 ml per ray, 25-gauge needle, ~60 seconds injection).

Control group:
Standard infiltration with 1% plain lignocaine only (identical volume, technique, and needle size).

Randomisation 1:1 using computer-generated allocation; allocation concealed.

Patients and the injecting surgeon are blinded until the moment of spray application.

## Intervention Type
Procedure/Surgery

## Primary outcome(s)
Injection pain measured using a 10-point Visual Analogue Scale (VAS) immediately after the first local anaesthetic infiltration

## Key secondary outcome(s)

1. Immediate adverse events (allergic reactions, vasovagal response, unusual sensations) recorded at the time of infiltration
2. Perioperative complications (infection, bleeding, neurovascular injury) recorded during and after PNA
3. Correlation between injection pain and patient demographic variables (age, sex, comorbidities) and disease severity (Tubiana grade) using Spearman's correlation coefficients

### Completion date
30/07/2026

## Eligibility

### Key inclusion criteria
1. Adults aged ≥18 years undergoing PNA for Dupuytren's disease
2. Disease affecting a single hand with one or more involved rays
3. Able to provide informed consent

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
100 Years

### Sex
Male

### Total final enrolment
94

### Key exclusion criteria
1. Known allergy or hypersensitivity to lignocaine
2. Prior sensory deficit or paraesthesia in the affected hand
3. Cognitive impairment affecting reliable pain assessment
4. Inability to provide informed consent

### Date of first enrolment
02/10/2024

### Date of final enrolment
15/06/2026

# Locations

**Countries of recruitment**
Australia

**Study participating centre**
**Frankston Hospital**
2 Hastings Road
Melbourne
Australia
3199

# Sponsor information

**Organisation**
Peninsula Health

**ROR**
https://ror.org/02n5e6456

# Funder(s)

**Funder type**
Industry

**Funder Name**
Peninsula Health

# Results and Publications

**Individual participant data (IPD) sharing plan**
The datasets generated during and/or analysed during the current study will be available upon reasonable request from the corresponding author (Dr Ishith Seth, ishithseth1@gmail.com). Data will be de-identified and anonymised prior to sharing. Access will be granted to researchers for academic purposes only, subject to approval by Peninsula Health Human Research Ethics Committee. Data will be available beginning 24 months after publication of the primary results and for a period of 5 years.

**IPD sharing plan summary**
Available on request

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | | | 20/08/2025 | No | Yes |