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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
Recruiting

Registration date
18/09/2025

Overall study status
Ongoing

Last Edited
20/08/2025

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] 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

Study website
Not applicable

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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)

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment, Safety, Efficacy

Participant information sheet
See study outputs table

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

Secondary outcome measures
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

Overall study start date
01/07/2024

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
100 Years

Sex
Male

Target number of participants
200

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

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Sponsor type
Industry

Website
https://www.peninsulahealth.org.au

ROR
https://ror.org/02n5e6456

Funder(s)

Funder type
Industry

Funder Name
Peninsula Health

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal and presentation at national and international plastic and hand surgery meetings.

Intention to publish date
30/10/2025

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