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Sodium bicarbonate buffering and needle gauge in percutaneous needle aponeurotomy: A blinded controlled trial evaluating injection pain reduction

Submission date
04/11/2025

Recruitment status
No longer recruiting

Registration date
07/12/2025

Overall study status
Completed

Last Edited
21/11/2025

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
Injecting local anaesthetic into the palm during percutaneous needle aponeurotomy (PNA) for Dupuytren's disease can be uncomfortable. This study aims to find out whether mixing (buffering) lignocaine with sodium bicarbonate can reduce the pain felt during the injection, and whether the size of the needle used (25G or 27G) affects how painful the injection feels.

Who can participate?
Adults aged 18 years or older with Dupuytren's disease affecting one hand and who are scheduled to undergo PNA can take part in the study.

What does the study involve?
Participants will receive a local anaesthetic injection in the palm before their PNA procedure. They will be randomly allocated to receive either standard 1% lignocaine or lignocaine that has been mixed with sodium bicarbonate. The injection will be given using either a 25G or a 27G needle. Participants will be asked to rate the level of pain they feel during the needle insertion and during the injection using a simple 0–10 pain scale. The procedure will continue as normal, and no extra visits are required. The study is single-blind, meaning the participant does not know which type of anaesthetic they receive.

What are the possible benefits and risks of participating?
There is no guaranteed direct benefit to taking part, but the information gained may help improve patient comfort during future hand procedures. All anaesthetic solutions used in this study are routinely used in clinical practice, and the risks are minimal. Possible side effects include mild discomfort from the injection, temporary numbness, or rare allergic reactions. Participation does not involve any additional cost or significant added risk beyond standard care.

Where is the study run from?
The study is being carried out at Peninsula Health, Frankston Hospital, in Victoria, Australia.

When is the study starting and how long is it expected to run for?
The study is expected to begin in early 2025 and will run for approximately 6 months, until recruitment and data collection are complete.

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Ishith Seth
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Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
A single-centre, single-blind controlled trial evaluating the effect of sodium bicarbonate-buffered versus plain lignocaine and needle gauge on injection pain during percutaneous needle aponeurotomy for Dupuytren’s disease

Acronym
BAPNA

Study objectives
The primary objective of this study is to determine whether buffering 1% lignocaine with 8.4% sodium bicarbonate reduces patient-reported injection pain during percutaneous needle aponeurotomy (PNA) for Dupuytren’s disease when compared with plain 1% lignocaine.

Secondary objectives are to:
1. Evaluate whether needle gauge (25G versus 27G) influences needle insertion pain during local anaesthetic administration for PNA.
2. Assess whether demographic factors (age and sex) are associated with variation in pain scores during injection.
3. Record the incidence of any immediate adverse events related to the administration of buffered or plain lignocaine.

Hypotheses:
Primary hypothesis: Buffered 1% lignocaine results in significantly lower patient-reported injection pain scores compared with plain 1% lignocaine during PNA.
Secondary hypothesis: Needle gauge (25G versus 27G) does not produce a clinically significant difference in needle insertion pain during PNA.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/10/2025, Peninsula Health HREC (Research Governance Office, 2 Hastings Road, Frankston, Melbourne, 3199, Australia; +61 397847777; iseth@phcn.vic.gov.au), ref: HREC /116536/PH-2025-491800

Primary study design
Interventional

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

Study type(s)
Efficacy, Treatment

Health condition(s) or problem(s) studied
Dupuytren’s disease requiring percutaneous needle aponeurotomy in adult patients.

Interventions
Participants will be randomly allocated to receive either 1% plain lignocaine or 1% lignocaine buffered with 8.4% sodium bicarbonate (10:1 ratio) for local anaesthetic infiltration during percutaneous needle aponeurotomy. Injections will be administered using either a 25-gauge or 27-gauge needle, with allocation concealed and the injecting surgeon blinded to group assignment. The anaesthetic will be delivered into the subcutaneous plane of the palm at standardised injection sites, with 4 mL infiltrated over approximately 60 seconds for the initial injection.

Randomisation was performed using a computer-generated random sequence prepared by a co-investigator not involved in injections or outcome assessment. Allocation was concealed using sealed, opaque, sequentially numbered envelopes, opened only at the time of patient preparation. The injecting surgeon remained blinded to the allocation.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Patient-reported pain during local anaesthetic infiltration measured using a 0–10 Visual Analogue Scale (VAS) at the time of injection

Key secondary outcome(s)
1. Pain at needle puncture measured using a 0–10 Visual Analogue Scale (VAS) at the moment of needle insertion
2. Incidence of immediate adverse events (e.g., allergic reaction, vasovagal response) recorded during and up to 30 minutes after the procedure
3. Difference in pain scores during needle insertion between 25G and 27G needles measured using a 0–10 Visual Analogue Scale (VAS) at the time of injection
4. Association between patient demographic factors (age and sex) and pain scores during local anaesthetic infiltration measured using a 0–10 Visual Analogue Scale (VAS) at the time of injection

Completion date
30/06/2026

Eligibility

Key inclusion criteria
1. Adults aged 18 years or older
2. Clinical diagnosis of Dupuytren’s disease requiring percutaneous needle aponeurotomy
3. Disease affecting a single hand
4. Able to provide informed consent
5. Able to understand study procedures and complete pain scoring assessments

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria

1. Known allergy or hypersensitivity to lignocaine or sodium bicarbonate
2. Previous sensory deficit or paraesthesia in the affected hand
3. Local infection at or near the planned injection site
4. Cognitive impairment that may affect the ability to provide informed consent or reliably report pain scores
5. Inability to understand study procedures or complete Visual Analogue Scale (VAS) assessments

Date of first enrolment
21/10/2025

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Australia

Study participating centre
Peninsula Health
2 Hastings Road
Melbourne
Australia
3199

Sponsor information

Organisation
Peninsula Health

ROR
https://ror.org/02n5e6456

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be available upon reasonable request from the corresponding author, Dr Ishith Seth (ishithseth1@gmail.com). De-identified individual participant data (including pain scores, demographic variables, and adverse event data) will be available beginning 6 months after publication of the study results and for up to 5 years thereafter. Data will be shared with researchers for ethically approved scientific purposes, following submission of a brief proposal outlining the intended use. Only anonymised data will be provided, and no information that could identify individual participants will be shared.

IPD sharing plan summary

Available on request