ISRCTN11819634 https://doi.org/10.1186/ISRCTN11819634

Ultrasound-guided needle knife release

Submission date
23/10/2024

Recruitment status
No longer recruiting

Registration date
04/11/2024

Overall study status
Completed

Last Edited
01/11/2024

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
This study focuses on a common hand condition called stenosing tenosynovitis of the flexor pollicis longus (FPL), which causes painful locking or jamming of the thumb. The aim is to evaluate the effectiveness and safety of a new treatment method called ultrasound-guided needle knife release.

Who can participate?
Patients with confirmed cases of stenosing tenosynovitis of the FPL, diagnosed through clinical examination and ultrasound, can participate.

What does the study involve?
The study involves 60 patients who are randomly divided into three groups: one group receives the ultrasound-guided needle knife release, another group receives traditional conservative treatment, and the third group undergoes open surgery. Participants' progress is monitored and compared across these groups.

What are the possible benefits and risks of participating?
The potential benefits include reduced pain and improved thumb function, especially for those receiving the needle knife release. The risks are minimal, with no serious adverse events reported. The needle knife release group showed better outcomes and fewer complications compared to the conservative treatment group.

Where is the study run from?
People's Hospital of Lvliang City (China)

When is the study starting and how long is it expected to run for?
January 2023 to June 2024.

Who is funding the study?
The study is funded by the People's Hospital of Lvliang City (China)

Who is the main contact?
Wenyan Xue, xue_wenyan@163.com

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
Nil known

Study information

Scientific Title
Ultrasound-guided needle knife release for the treatment of stenosing tenosynovitis of the flexor pollicis longus: a prospective randomized controlled trial

Study objectives
This study aimed to evaluate the efficacy and safety of ultrasound-guided needle knife release in the treatment of stenosing tenosynovitis of the flexor pollicis longus (FPL).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 20/07/2024, People's Hospital of Lvliang City (No. 277, Lishibinhe North Middle Road, Lvliang, 033099, China; +86 (0)358 8245001; llsrmyyxck@163.com), ref: LY2024-32

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment, Safety, Efficacy

Participant information sheet

Health condition(s) or problem(s) studied
Ultrasound-guided needle knife release in the treatment of stenosing tenosynovitis of the flexor pollicis longus (FPL)

Interventions
60 patients with clinically and ultrasonographically confirmed stenosing tenosynovitis of the FPL were randomly allocated to three groups: ultrasound-guided needle knife release (n = 20), traditional conservative treatment (n = 20), and open surgery (n = 20).

1. Ultrasound-guided needle knife release group
Patients in this group underwent ultrasound-guided percutaneous release of the A1 pulley using a 21-gauge needle knife (Hanzhang Medical Supplies Co., Ltd., Shanghai, China). Under local anesthesia with 1% lidocaine, the procedure was performed by a single experienced musculoskeletal radiologist (X.Y.Z., with 10 years of experience in musculoskeletal ultrasound) in day surgery units of outpatient settings.
A high-frequency linear array transducer (18-5 MHz, Aplio 500; Canon Medical Systems Corporation, Tochigi, Japan) was used to identify the thickened A1 pulley in the longitudinal and transverse planes. The knife broke the constricting tissue around the tendon sheath. After locating the A1 pulley, a needle knife was inserted through the A1 pulley and into the flexor tendon. A sweeping motion of the needle knife on the A1 pulley was used to divide the A1 pulley longitudinally. The patient's thumb should not be moved during the release process to avoid damaging his tendons and nerves. The disappearance of a gating sound and active range of motion could be confirmed as fully releasing the afflicted finger. The procedure was repeated if necessary to ensure adequate release, as confirmed by ultrasonography. The puncture site was dressed with sterile adhesive bandages, and the patients were allowed to use their hands immediately after the procedure.

2. Traditional conservative treatment group
Patients in this group received oral NSAIDs (celecoxib 200 mg daily for 4 weeks) and night splinting with a custom-molded thermoplastic splint maintaining the metacarpophalangeal joint in a neutral position for 4 weeks. A single corticosteroid injection (1 mL of 40 mg/mL methylprednisolone acetate) was administered into the tendon sheath at the level of the A1 pulley under ultrasound guidance by the same radiologist who performed the needle knife release.

3. Open surgery group
Open surgical release of the A1 pulley was performed by a single hand surgeon (A.B.C., with 15

years of experience in hand surgery) under local anesthesia with 1% lidocaine. A 1.5-cm transverse incision was made at the level of the metacarpophalangeal joint crease. The A1 pulley was identified and completely transected. The skin was closed with 5-0 nylon sutures, and a sterile dressing was applied. Patients were instructed to keep the hand elevated and to perform gentle range of motion exercises starting on the first postoperative day.

Randomisation:
Eligible participants were randomly allocated to three groups in a 1:1:1 ratio using a computer-generated randomization list with permuted blocks of six. The allocation sequence was concealed in sequentially numbered, opaque, sealed envelopes, which were opened by a research assistant immediately before the intervention. Participants and outcome assessors were blinded to the group allocation, but blinding of the treating physicians was not feasible due to the nature of the interventions.

Intervention Type
Procedure/Surgery

Primary outcome measure
Severity of triggering assessed using the Quinnell grading system at time at baseline, 1 week, 1 month, and 3 months after the intervention

Secondary outcome measures
Evaluated at baseline, 1 week, 1 month, and 3 months post-intervention:
1. Pain intensity assessed using a Visual Analog Scale (VAS) ranging from 0 (no pain) to 10 (worst imaginable pain)
2. Patient satisfaction assessed using a 5-point Likert scale (1, very dissatisfied; 2, dissatisfied; 3, neutral; 4, satisfied; 5, very satisfied)
3. Grip strength measured using a Jamar dynamometer (Patterson Medical, Warrenville, IL, USA)
4. Pinch strength measured using a pinch gauge (B&L Engineering, Santa Ana, CA, USA)
5. Disabilities of the Arm, Shoulder and Hand (DASH) score
6. Complications, such as infection, nerve injury, and tendon rupture measured by two blinded hand therapists who were not involved in the treatment process

Overall study start date
01/01/2023

Completion date
30/06/2024

Eligibility

Key inclusion criteria
1. Adults aged 18-70 years
2. Clinically and ultrasonographically confirmed stenosing tenosynovitis of the FPL (Quinnell grade ≥2, A1 pulley thickness >1 mm)
3. Symptoms present for at least 3 months
4. Failure of conservative treatment (NSAIDs, splinting, or corticosteroid injections) for at least 6 weeks

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Total final enrolment
60

Key exclusion criteria
1. Secondary trigger thumb due to underlying conditions (e.g., diabetes mellitus, rheumatoid arthritis, gout)
2. Previous surgical intervention for trigger thumb
3. Concomitant hand disorders (e.g., carpal tunnel syndrome, de Quervain's tenosynovitis)
4. Severe cardiovascular, pulmonary, or neurological comorbidities
5. Inability to comply with the study protocol or follow-up schedule

Date of first enrolment
01/01/2023

Date of final enrolment
01/06/2024

Locations

Countries of recruitment
China

Study participating centre
People's Hospital of Lvliang City
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Sponsor information

Organisation
People's Hospital of Lvliang City

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
People's Hospital of Lvliang City

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
01/06/2025

Individual participant data (IPD) sharing plan
The individual participant data can be request from the corresponding author.
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IPD sharing plan summary
Available on request