Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of functional outcomes in Zone 1 flexor tendon injuries treated with classical transosseous versus paraosseous pull-out button techniques: A randomized, parallel-group, double-blinded (participant and outcome assessor) clinical trial

Protocol summary

Study aim

To critically evaluate and compare the functional outcomes, biomechanical efficacy, and complication rates of Zone 1 FDP tendon repairs utilizing two distinct pull-out button placement techniques: the classical bone-penetrating (transosseous) method versus the tissue-sparing (paraosseous) method.

Design

A parallel-group, randomized, double-blind, actively controlled clinical trial comprising 50 participants.

Settings and conduct

The trial will be conducted at Shohadaye Ashayer Hospital, Khorramabad, Iran. Following strict inclusion, a SNOSE protocol will ensure allocation concealment. All surgical procedures will be standardized and performed by a single board-certified reconstructive subspecialist. The study enforces double-blinding protocols: patients are blinded to the allocated surgical technique, and all post-operative evaluations are recorded independently by a blinded plastic surgeon.

Participants/Inclusion and exclusion criteria

The target population comprises adults (18-60 years) presenting with acute (<72 hours) Zone 1 FDP tendon lacerations or avulsions (gap <1 cm) indicated for primary surgical repair. Exclusion criteria apply to patients with confounding musculoskeletal injuries (crush trauma, intra-articular fractures), systemic diseases impairing tissue healing, or existing sensory neuropathies.

Intervention groups

Fifty eligible participants will be randomly allocated to either Group 1 (Classical Transosseous pull-out method, n=25) or Group 2 (Paraosseous paronychia-routed pull-out method, n=25).

Main outcome variables

Primary variables include patient-reported upper extremity disability (DASH score) and objective joint mobility (Modified Strickland Score). Secondary variables evaluate grip/pinch strength dynamometry, digital edema, pain severity (VAS), sensory recovery, and adverse events (nail dystrophies, infection, tendon re-rupture, adhesions).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230410057871N16**
Registration date: **2026-07-02, 1405/04/11**
Registration timing: **prospective**

Last update: **2026-07-02, 1405/04/11**
Update count: **0**

Registration date

2026-07-02, 1405/04/11

Registrant information

Name

Arian Karimi Rouzbahani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Not yet recruiting

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

Expected recruitment end date

2028-09-22, 1407/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of functional outcomes in Zone 1 flexor tendon injuries treated with classical transosseous versus paraosseous pull-out button techniques: A randomized, parallel-group, double-blinded (participant and outcome assessor) clinical trial

Public title

Comparing two surgical techniques for repairing flexor tendon injuries of the hand (Zone 1)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 60 years. Acute rupture or avulsion of the flexor digitorum profundus (FDP) tendon in Zone 1 Tendon gap/retraction of less than 1 cm Time elapsed from initial injury is strictly less than 72 hours

Exclusion criteria:

Unwillingness to participate or anticipated non-compliance with the follow-up protocol. Intra-articular fractures severely limiting baseline or potential range of motion. Severe crush injuries or concomitant cartilaginous damage. Current use of bone-depleting or immunosuppressive medications. History of congenital/acquired bone defects or conditions impairing wound healing (e.g., uncontrolled diabetes mellitus, chronic infections, autoimmune disorders, HIV/AIDS). Pregnancy. History of keloid formation or inadequate soft tissue coverage at the surgical site. Pre-existing conditions affecting the assessment of the contralateral digit (e.g., previous hand trauma, amputation, arthritis, congenital deformities, or baseline sensory impairments).

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization will be executed using a computer-generated random number sequence. Allocation concealment will be strictly maintained using sequentially numbered, opaque, sealed envelopes (SNOSE). Envelopes will be opened by a non-surgical staff member in the operating room just prior to the intervention to reveal the designated technique (A: Classical transosseous, B: Paraosseous).

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the nature of the surgical intervention, the operating surgeon cannot be blinded. Therefore, this trial is double-blinded targeting the participants and the outcome assessors. Patients will be unaware of the specific button-placement technique used. Post-operative assessments (functional scoring, ROM, complications) will be conducted by an independent plastic surgeon who is entirely blinded to group allocation.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Lorestan University of Medical Sciences

Street address

Moallem Street, Shahid Anushirvan Rezaei Square, University of Medical Sciences

City

Khorramabad

Province

Lorestan

Postal code

6813833946

Approval date

2026-06-02, 1405/03/12

Ethics committee reference number

IR.LUMS.REC.1405.143

Health conditions studied

1

Description of health condition studied

پارگی تاندون‌های فلکسور دست، آسیب‌های زون ۱، FDP ترمیم تاندون دست

ICD-10 code

S66.1

ICD-10 code description

Injury of flexor muscle, fascia and tendon of other and unspecified finger at wrist and hand level

Primary outcomes

1

Description
Functional disability and upper extremity functional outcome.
Timepoint
At 6, 12, and 24 weeks post-operation.
Method of measurement
Validated 30-item Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire.

2

Description
Range of motion of the Distal and Proximal Interphalangeal (DIP and PIP) joints.
Timepoint
At 12 and 24 weeks post-operation.
Method of measurement
Modified Strickland Score criteria.

Secondary outcomes

1

Description
Grip and pinch strength (compared to the uninjured contralateral hand).
Timepoint
At 12 and 24 weeks post-operation.
Method of measurement
Jamar hydraulic hand dynamometer and Jamar hydraulic pinch gauge.

2

Description
Digit swelling/edema.
Timepoint
At 3, 6, 12, and 24 weeks post-operation.
Method of measurement
Measured via a finger circumference gauge (in millimeters) compared to the contralateral digit.

3

Description
Post-operative pain severity
Timepoint
At structured post-operative follow-up visits.
Method of measurement
10-point Visual Analogue Scale (VAS).

4

Description
Incidence of complications (nail bed deformity, chronic pain, wound infection, adhesion, tendon re-rupture).
Timepoint
Monitored continuously up to 24 weeks post-operation
Method of measurement
Standardized clinical examination by a blinded assessor.

Intervention groups

1

Description
Intervention group: Patients in this active control group will undergo Zone 1 FDP tendon repair utilizing the conventional pull-out method. Core sutures will be passed through drill holes created from the volar cortex extending through the dorsal aspect of the distal phalanx. The sutures will then be tied and secured over a button positioned directly on the nail plate.
Category
Treatment - Surgery

2

Description
Control group: Patients in this experimental intervention group will undergo FDP tendon repair via a paraosseous pull-out approach. To preserve the integrity of the nail bed and the distal phalanx bone, the sutures will be routed laterally through the paronychia (the soft tissue adjacent to the nail) without drilling the bone. The sutures are then secured to an externally placed button.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye Ashayer Hospital, Khorramabad, Iran
Full name of responsible person
Arian Karimi Rouzbahani
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Lorestan, Khorramabad, Moallem Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Khoram-Abad University of Medical Sciences
Full name of responsible person
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Khorramabad, Kamalvand, Km 4 Khorramabad–Borujerd Road, Pardis Academic Complex, Lorestan University of Medical Sciences, Deputy of Research and Technology

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Khoram-Abad University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
Arian Karimi Rouzbahani

Position
Medical doctor

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Data set title: “Individual Participant Data (IPD) for the trial comparing FDP tendon repair by transosseous versus paraosseous pull-out methods.” Data to be shared: All collected deidentified IPD underlying the results reported in the article, including primary and secondary outcome measures (VAS scores, chronic nail-bed pain, nail deformity, and range of motion/ROM), together with the data dictionary.

When the data will become available and for how long

Timing and Duration of Data Availability The deidentified Individual Participant Data (IPD) and associated documentation for this study will become available six months after final publication of the manuscript in the target journal (expected in late 2026 or early 2027), through a reputable public repository (e.g., Figshare or Zenodo). Duration of availability: The data will be retained and accessible for a minimum of five years from the date of publication. Conditions of access: All applicants may request access by submitting a written request to the Principal Investigator and signing a Data Use Agreement, at no cost.

To whom data/document is available

Description of Persons and Institutions Eligible to Receive Deidentified IPD and Supporting Information The deidentified Individual Participant Data (IPD) and accompanying supporting materials (including the data dictionary, analysis methodology, and statistical reports) will be made available to all researchers, scientists, and professionals in fields related to orthopedic surgery, hand surgery, microsurgery, and clinical sciences—regardless of whether they work in academic institutions, government agencies, industry, pharmaceutical companies, or medical technology firms. Conditions and Requirements for Access: Purpose of Use: Applicants must specify the intended purpose. Permitted uses include: academic research, medical product development, meta-analyses, health evaluations, and education. Data Use Agreement (DUA): All applicants must sign a DUA committing to use the data solely for approved purposes. Intellectual Property: The data remain the property of the original investigators. Applicants may not sell or redistribute the data. Ownership of Results: Results derived from the data belong to the requesting researcher, provided that the original investigators are acknowledged as collaborators or sources in any final publication. No Re-identification: Applicants must commit to not attempting to re-identify individuals from the deidentified dataset. Oversight: The original investigators retain oversight rights and may revoke access in case of violation. Notes: Commercial use is permitted, subject to the above terms. Uses that violate patient privacy or conflict with Iranian health and ethical regulations are prohibited.

Under which criteria data/document could be used

Access Criteria and Data Sharing Mechanism Types of analyses permitted: Secondary analyses to address new research questions related to FDP tendon repair Meta-analyses and systematic reviews Validation studies and comparisons with similar datasets Predictive modeling or advanced statistical analyses Educational use in academic settings (with confidentiality safeguards) Criteria for evaluating requests: Scientific qualifications of the applicant: Documented research track record, publications, and relevant expertise Clarity of research objective: Submission of a clear study protocol or research proposal Scientific justification for data access: Demonstration of the necessity to access IPD Adherence to ethical principles: Commitment to non-re-identification and privacy protection No conflict of interest: Absence of commercial or competitive interests that compromise scientific integrity Access mechanism: Applicants must submit a written request to the Principal Investigator including: Brief project description (maximum 500 words) List of required data elements Letter of introduction from affiliated institution Academic CV Request reviewers: Principal Investigator and the core research team Review timeline: Maximum 4 weeks from receipt of complete application Data delivery: Following approval and signing of the Data Use Agreement, data will be provided via secure download link or confidential repository Reporting: Applicants must provide a summary of findings to the research team upon completion and properly cite the data source in any publications Grounds for rejection: Insufficient scientific justification Clear conflict of interest or unauthorized commercial use Failure to meet ethical or legal requirements

From where data/document is obtainable

How to Access Data and Contact Information To request access to the study data, applicants may contact the Principal Investigator through one of the following methods: Principal Investigator: [Full Name] [Title and Institutional Affiliation] Preferred method of communication: Email Contact Information: Email: [email address] Telephone: [phone number with country code] Fax: [fax number - if available] Postal Address:[Department/Division][Institution/Hospital/University Name][Full Postal Address][City, Postal Code, Country] Online Access: Project Website: [URL - if available] Data Repository: [Repository name and URL, e.g., Figshare, Zenodo, Dryad - if available] Digital Object Identifier (DOI): [DOI for the dataset - if assigned] Required Documentation for Request: Completed application form (available via email) Research protocol or study proposal Applicant’s academic CV Letter of introduction from affiliated institution Signed draft Data Use Agreement Response Time: Requests will be reviewed and responded to within 4 weeks.

What processes are involved for a request to access data/document

Step-by-Step Data Access Process and Estimated Timeline Step 1 — Initial Contact and Form Request The applicant emails the Principal Investigator to request the formal application form and the draft Data Use Agreement. Estimated time: 1–3 business days to receive a response and the forms Step 2 — Document

Preparation by Applicant The applicant prepares the research protocol, academic CV, institutional letter of introduction, and completed application form. Estimated time: 1–2 weeks (depending on how quickly the institutional letter is obtained) Step 3 — Submission of Complete Application The full document set is submitted by email. The Principal Investigator confirms receipt. Estimated time: 1–2 business days for acknowledgment Step 4 — Scientific and Ethical Review The Principal Investigator and core team evaluate scientific qualifications, research justification, and ethical compliance. Additional information may be requested. Estimated time: up to 4 weeks from receipt of the complete application Step 5 — Data Use Agreement Execution Upon approval, the DUA is finalized and signed by both parties (and institutional legal/research offices if required). Estimated time: 1–3 weeks (depending on the legal processes of both institutions) Step 6 — Data Delivery After the DUA is signed, data are provided via a secure download link or confidential repository. Estimated time: 3–7 business days Total approximate process time: about 8–12 weeks (from initial contact to data receipt) Note: Factors affecting the timeline include the applicant's speed in preparing documents, the need for institutional ethics committee review, and the complexity of DUA legal negotiations.

Comments