

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of Treatment Outcomes in Patients with Insertional Achilles Tendinopathy (IAT) Using Two Osteotomy Techniques With and Without Tendon Reinsertion

Protocol summary

Study aim

To compare the treatment outcomes of patients with insertional Achilles tendinopathy using two osteotomy techniques with and without Achilles tendon reinsertion.

Design

A controlled, parallel-group, unblinded, randomized, phase 3 clinical trial on 42 patients. The Sealed Envelope online software was used for randomization using randomized blocks.

Settings and conduct

This study will be conducted in the Orthopedics Department of Akhtar Hospital, Tehran. Patients with Achilles tendon insertion tendinopathy who meet the inclusion criteria will be enrolled and randomly assigned to two groups. In the first group, after osteotomy, the Achilles tendon is anatomically reattached to the calcaneus bone (reinsertion). In the second group, osteotomy is performed but tendon reattachment is not performed. Patients will be followed up and evaluated at 3, 6, and 9 months after surgery. Blinding was not performed in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with tendinopathy at the Achilles tendon junction with symptoms of pain, swelling, and tenderness in the heel, with lateral ankle radiography, involvement of less than 50% of the Achilles tendon-calcaneus junction. Exclusion criteria: failure to refer for follow-up or unwillingness to participate in the study.

Intervention groups

Group 1: After osteotomy, the Achilles tendon is completely separated and after tendinous debridement, the tendon is re-sutured to its anatomical location by passing a thread through the tunnel created in the calcaneus bone (reinsertion is performed). Group 2: After osteotomy and removal of excess tissue, the Achilles tendon is not re-sutured to the calcaneus bone and

reinsertion is not performed.

Main outcome variables

Functional score based on AOFAS ankle-hindfoot questionnaire, pain intensity based on VAS scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250607066100N1**

Registration date: **2025-07-04, 1404/04/13**

Registration timing: **registered_while_recruiting**

Last update: **2025-07-04, 1404/04/13**

Update count: **0**

Registration date

2025-07-04, 1404/04/13

Registrant information

Name

Ali Motevallizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 25719

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-10, 1404/03/20

Expected recruitment end date

2026-03-21, 1405/01/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of Treatment Outcomes in Patients with Insertional Achilles Tendinopathy (IAT) Using Two Osteotomy Techniques With and Without Tendon Reinsertion

Public title
Comparison of Two Surgery Techniques of Osteotomy with and Without Tendon Reinsertion in the treatment of tendinopathy.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Clinical signs of Achilles tendinopathy (pain, swelling, and tenderness in the heel) Confirmation of IAT diagnosis with lateral ankle radiography Less than 50% involvement of the Achilles tendon-calcaneus junction on surgical evaluation
Exclusion criteria:
Patients not returning for follow-up Patient unwillingness to participate in the study and request to withdraw

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, randomization is performed using block randomization with variable block sizes (2, 4, and 6 participants). The unit of randomization is individual, meaning each patient is independently assigned to one of the two treatment groups. Stratified randomization is not used in this trial. The random allocation sequence was generated using the online software Sealed Envelope. After determining the total sample size (42 participants) and specifying the possible block sizes, the allocation sequence was created and placed in sealed, opaque envelopes. On the day of surgery, these envelopes are handed to the surgeon without prior disclosure to ensure allocation concealment.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Faculty of Medicine, Shahid Beheshti University of Medical Sciences

Street address

Arabi street, Velenjak

City

Tehran

Province

Tehran

Postal code

193954631

Approval date

2025-05-27, 1404/03/06

Ethics committee reference number

IR.SBMU.MSP.REC.1404.146

Health conditions studied

1

Description of health condition studied

Insertional Achilles Tendinopathy

ICD-10 code

M76.6

ICD-10 code description

Achilles tendinitis

Primary outcomes

1

Description

Foot and ankle functional score

Timepoint

At 3, 6, and 9 months after surgery

Method of measurement

AOFAS ankle-hindfoot questionnaire

Secondary outcomes

1

Description

pain severity

Timepoint

At 3, 6, and 9 months after surgery

Method of measurement

VAS scale

2

Description

complication

Timepoint

After surgery

Method of measurement

History and clinical examination

Intervention groups**1****Description**

Intervention group: After the osteotomy, the Achilles tendon is completely separated and, after tendinous debridement, the tendon is re-sutured to its anatomical location (reinsertion) by passing a thread through the tunnel created in the calcaneus bone.

Category

Treatment - Surgery

2**Description**

Intervention group: After the osteotomy and removal of excess tissue, the Achilles tendon is not re-sutured to the calcaneus bone and reinsertion is not performed.

Category

Treatment - Surgery

Recruitment centers**1****Recruitment center****Name of recruitment center**

Akhtar Hospital

Full name of responsible person

Aliasghar Alamian

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Azar Dead End, Sharifi Manesh Street, Pol-e Roomi Street, Shariati Street

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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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

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ali Motevalizadeh

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Maintaining patient privacy and confidentiality

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be 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

Only information related to the study protocol, statistical analysis plan, and clinical study report will be made available to other researchers to guide future studies (and not publicly).

When the data will become available and for how long

After publication of the article

To whom data/document is available

Researchers, students, and professors in the field of orthopedics

Under which criteria data/document could be used

For use in future research and if the source is cited.

From where data/document is obtainable

Corresponding author Dr. Aliasghar Alamian
Shahramalamian@gmail.com

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

Send a request via email to the corresponding author, stating the reason for the request and how the data will be used.

Comments