Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

Phone
+98 21 25719

Email address
dr.alimotevallizadeh@gmail.com

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
Street address
Azar Dead End, Sharifi Manesh Street, Pol-e Roomi Street, Shariati Street
City
Tehran
Province
Tehran
Postal code
1964714953
Phone
+98 21 2260 8246
Email
akhtarhospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Arabi street, Velenjak
City
Tehran
Province
Tehran
Postal code
193954631
Phone
+98 21 23871
Email
info@sbmu.ac.ir
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
Street address
Arabi street, Velenjak
City
Tehran
Province
Tehran
Postal code
193954631
Phone
+98123871
Email
dr.alimotevallizadeh@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Aliasghar Alamian

Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
Street address
Akhtar Advanced Orthopedic Specialty Center, Azar Dead End, Sharifi Manesh Street, Pol-e Roomi Street, Shariati Street
City
Tehran
Province
Tehran
Postal code
1964714953
Phone
+98 21 2260 8246
Email
Shahramalamian@gmail.com

Person responsible for updating data

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
Street address
Arabi street, Velenjak
City
Tehran
Province
Tehran
Postal code
193954631
Phone
+98 21 23871
Email
dr.alimotevallizadeh@gmail.com

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 ofthe 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