

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the ankle surgery results with tightrope implant and syndesmosis three-cortical screw in patients with ankle syndesmosis injury referring to Alzahra and Kashani hospitals in 2015-17

Protocol summary

Study aim

Comparison of syndesmosis injuries surgical outcomes using tight rope versus tricortical screw

Design

Clinical trial, with control group, with parallel group, double blinded, randomized

Settings and conduct

The study was conducted in Alzahra and Kashani hospitals of Isfahan. Patients were divided in two groups of tricortical screw and tightrope approach through randomization using random allocation software. Patients and clinical physician were blinded to the type of surgery. Tricortical screw: within 1.5cm above ankle joint; fibula and tibia were bilaterally pierced and tricortical screw was fixed. Tightrope group: Tibia and fibula were pierced throughout of the cortex, tightrope fixation was performed from the medial skin to the other side. Then results were compared within 6, 12 and 18 months following the surgery regarding range of motion and American Foot and Neck Orthopedic Society.

Participants/Inclusion and exclusion criteria

Patients with syndesmosis injury who were over 18 years were included. Patients with concurrent talus and calcaneus fracture, previous history of ankle surgery and who had diabetes mellitus and/or rheumatoid arthritis unmet inclusion criteria.

Intervention groups

Tricortical screw: within 1.5cm above ankle joint, fibula and tibia were bilaterally pierced and tricortical screw was fixed. Tightrope group: Tibia and fibula cortex were totally pierced, medial skin was pierced and tightrope was fixed to the other side.

Main outcome variables

Pain; Plantar flexion; Dorsal flexion; Sagittal motion; gate; Hind foot motion; Function; Movement limitation; maximum walk; maximum surface

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190219042756N1**

Registration date: **2019-03-29, 1398/01/09**

Registration timing: **retrospective**

Last update: **2019-03-29, 1398/01/09**

Update count: **0**

Registration date

2019-03-29, 1398/01/09

Registrant information

Name

Sina Talebi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3444 7707

Email address

sinatalebi_3969@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

2015-10-23, 1394/08/01

Actual recruitment end date

2018-04-26, 1397/02/06

Trial completion date

2018-04-26, 1397/02/06

Scientific title

Comparison the ankle surgery results with tightrope implant and syndesmosis three-cortical screw in patients with ankle syndesmosis injury referring to Alzahra and Kashani hospitals in 2015-17

Public title

Comparison the ankle surgery results with tightrope implant and syndesmosis three-cortical screw in patients with ankle syndesmosis injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of above 18 years old Ankle syndesmosis injury

Exclusion criteria:

Concurrent talus and calcaneus fracture Previous history of ankle and peri-ankle tissue fracture Diabetes Mellitus Arthritis Rheumatoid

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: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were provided with numbers using Random Allocation software and considering whether even or odd number they were allocated to tightrope fixation or tightrope fixation approach respectively

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients were blinded to type of surgery and the person who assessed outcomes was blinded to type of surgery

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezarjarib Street

City

Isfahan

Province

Isfahan

Postal code

7346181746

Approval date

2017-07-01, 1396/04/10

Ethics committee reference number

ir.mui.rec.1396.4.420

Health conditions studied

1

Description of health condition studied

Ankle syndesmosis injury

ICD-10 code

S90.91

ICD-10 code description

Unspecified superficial injury of ankle

Primary outcomes

1

Description

American Orthopaedic Foot & Ankle Society Score

Timepoint

6, 12 and 18 months after surgical procedure

Method of measurement

Based on scoring system of American Orthopaedic Foot & Ankle Society

Secondary outcomes

empty

Intervention groups

1

Description

Control group: Tricortical screw: in this technique within 1.5 centimeters further than ankle, fibula and tibia cortex will be pierced and tricortical screw was fixed.

Category

Treatment - Surgery

2

Description

Intervention group: tightrope group: in this technique fibula and tibia cortex will be pierced and tightrope will be moved from medial holes to lateral ones and then flipped.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Alzahra Hospital
Full name of responsible person
Sina Talebi
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2

Recruitment center

Name of recruitment center
Kashani Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
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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

Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Sina Talebi
Position
Orthopedist
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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

Yes - There is a plan to make this available

Title and more details about the data/document

Data has been published as an article

When the data will become available and for how long

Following article publication as it has been accepted now

To whom data/document is available

Orthopedics projects with similar titles

Under which criteria data/document could be used

For University projects and in case of being in touch with corresponding author of the study

From where data/document is obtainable

Making touch with corresponding author of the study Dr. Sina Talebi

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

Keeping touch with the corresponding author and coordination with University

Comments