

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparing of posteromedial approach versus anteromedial approach in surgery of extra-articular distal tibia fractures

Protocol summary

Study aim

Comparing of posteromedial versus anteromedial approaches in surgery of extra-articular distal tibia fractures

Design

Patients were diagnosed with extra-articular(close or open) tibial fractures after hospitalization and skin preparation with a posteromedial or anteromedial approach, they were randomly selected. The age and sex of the patient and the contact number were entered into the questionnaire. Subsequent illnesses with a history of drug use, as well as, Fractal typing according to the AO classification, typing soft tissue status were determined by two professors separately and recorded in the questionnaire

Settings and conduct

Patients diagnosed with open-ended or closed-bed tibial distal fracture in Taleghani Hospital of Tehran entered the study. The two intervention groups undergo surgery and the surgical results are compared.

Participants/Inclusion and exclusion criteria

inclusion criteria: extra-articular distal tibia fractures, Age: 16 -75 years old exclusion criteria: 1) connective tissue disease 2) Peripheral neurovascular disease 3) Uncontrol D.M 4) Previous scar in the ankle and distal tibia, 5) Previous surgery and fractures in the ankle and distal tibia Previous scar 6) Corticosteroids MTX & Chemotherapeutic drugs 7) Intraarticular fractures 8) Pathology fractures 9) Vascular damage 10) Compartment syndrome

Intervention groups

Intervention 1: Anteromedial Intervention 2: Posteromedial distal tibia approaches

Main outcome variables

1) superficial skin infection 2) deep infection 3) superficial skin necrosis 4) deep skin necrosis and plate exposure and needs skin graft or flap 5) wound dehiscence 6) incisional injury to the neurovascular bundle 7) non union 8) delay union 9) malunion 10) mal

alignment 11) internal fixation loosening 12) skin sense examination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180306038971N3**

Registration date: **2020-12-17, 1399/09/27**

Registration timing: **retrospective**

Last update: **2020-12-17, 1399/09/27**

Update count: **0**

Registration date

2020-12-17, 1399/09/27

Registrant information

Name

Mohammad Ali Okhovatpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 2222

Email address

okhovatpour@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

2018-09-23, 1397/07/01

Actual recruitment end date

2019-09-23, 1398/07/01

Trial completion date

2019-09-23, 1398/07/01

Scientific title

Comparing of posteromedial approach versus anteromedial approach in surgery of extra-articular distal tibia fractures

Public title

Comparing postero-medial approach versus antero-medial approach in surgery of extra articular distal tibia fractures in Taleghani hospital_Tehran

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

extra articular distal tibia fractures Age : 16 -75 years old

Exclusion criteria:

Intra articular fractures Patologic fractures Vascular damage Uncontrol Diabetes mellitus Corticosteroids drugs Previous surgery and fractures in this area Previous scar Peripheral neurovascular disease connective tissue disease Compartment syndrome chemotherapy

Age

From **16 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **32**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization for 2 intervention groups. The randomization method will be done using software, 20 random numbers for each intervention group. The researcher can not play a role in predicting the treatment of the disease and choosing the type of treatment. the random sequence will generate by software. Group 1: 20 Cases and Group 2: 20 cases.

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 Shahid Beheshti University of Medical Sciences

Street address

Research Deputy, medical school, Arabi Ave, , Velenjak , Tehran

City

Tehran

Province

Tehran

Postal code

1985717413

Approval date

2017-09-04, 1396/06/13

Ethics committee reference number

IR.SBMU.RETECH.1396.324

Health conditions studied**1****Description of health condition studied**

Extra articular distal Tibia Fracture

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Evaluation of post operation complication due to approaches

Timepoint

Six weeks, 3 months, 6 months, and 12 months after surgery

Method of measurement

American Orthopaedic Foot and Ankle Society (AOFAS) Ankle Questionnaire

2**Description**

Tscherne score

Timepoint

Six weeks, 3 months, 6 months, and 12 months after surgery

Method of measurement

Questionnaire

3**Description**

Fracture type, according to AO classification

Timepoint

Once, at the beginning of the study

Method of measurement

Radiologic image

4

Description

Infection

Timepoint

Six weeks, 3 months, and 6 months after surgery

Method of measurement

Wound examination

Secondary outcomes

1

Description

AOFAS (Ankle score). This instrument combines functional outcome and pain.

Timepoint

Six weeks, 3 months, 6 months, and 12 months after surgery

Method of measurement

American Orthopaedic Foot and Ankle Society (AOFAS) Ankle Questionnaire

Intervention groups

1

Description

Intervention 1 group: patients have operated by posteromedial approaches in extra articular surgery

Category

Treatment - Surgery

2

Description

Intervention 2 group: Patients have operated by anteromedial approaches

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospital, Tehran

Full name of responsible person

Mohammad Ali Okhovatpour

Street address

Taleghani Hospital, Arabi Ave, Daneshjoo Blvd., Velenjak, Tehran

City

Tehran

Province

Tehran

Postal code

1985717413

Phone

+98 21 2243 2560

Email

okhovatpour@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohammad Ali Okhovatpour

Street address

Taleghani hospital.aarabi streest. velenjac.Tehran

City

Tehran

Province

Tehran

Postal code

1983969412

Phone

+98 21 2243 9937

Email

okhovatpour@sbmu.ac.ir

Grant name

Grant code / Reference number

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

No

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

Mohammad Ali Okhovatpour

Position

associated professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Taleghani Hospital, Arabi Ave., Daneshjoo Blvd., Velenjak, Tehran

City

Tehran

Province

Tehran

Postal code
1985717413
Phone
+98 21 2243 2560
Email
okhovatpour@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Ali Okhovatpour
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Orthopedics
Street address
Taleghani Hospital, Arabi Ave., Daneshjoo Blvd.,
Velenjak, Tehran
City
Tehran
Province
Tehran
Postal code
1985717413
Phone
+98 21 2243 2560
Email
okhovatpour@sbmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Ali Okhovatpour

Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Orthopedics
Street address
Taleghani Hospital, Arabi Ave., Daneshjoo Blvd.,
Velenjak, Tehran
City
Tehran
Province
Tehran
Postal code
1985717413
Phone
+98 21 2243 2560
Email
okhovatpour@sbmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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