

# 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

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### 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

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##### Postal code

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##### Phone

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##### 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

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##### Phone

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#### 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

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##### Province

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Beheshti University of Medical Sciences  
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**Position**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

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## 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