

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the Results of Tibial or Femoral Non-union Treatment with Two Methods "Internal Fixation + Autologous Bone Graft" and "Internal Fixation + Allogenic Umbilical Cord Mesenchymal Stem Cells"

Protocol summary

Study aim

Comparison of the Results of Tibia or Femur Non-union Treatment (Time taken until Union; Rate of union; Rate of Improvement in Pain and Function; Rate of Improvement in Hip, Knee and Ankle Range of Motion; Rate of Surgical Complications; and Satisfaction with Surgery) with two Methods: Autologous Cancellous bone graft + Internal Fixation" and "Allogeneic Mesenchymal Stem Cell Injection with Umbilical Cord Origin + Internal Fixation"

Design

Non-Randomised, Parallel Group, Clinical Trial with controlled group on 501 patients

Settings and conduct

This Study is a Prospective Interventional Study that is conducted on Patients with Tibia or Femur Non-union referred to Dr. Shariati Hospital. patient Information Including Demographic Information is recorded in the Relevant Checklists. The Patient is explained about the Two Treatment Methods and the Advantages and Disadvantages of each Method, and The Patient chooses One of the Treatment Methods at his own Discretion.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Having Tibia or Femur Non-union At Least 3 Months Between Fracture and Surgical Treatment
Consent of the Patient to Participate in the Study
Exclusion Criteria: Previous Surgery on the Thigh or Leg
Hip, Knee or Ankle Osteoarthritis Presence of Accompanying Injury in Thigh or Leg

Intervention groups

Patients undergo One of the Following Treatments:
"Internal Fixation + Autologous Cancellous Bone Graft"
or "Internal Fixation + Injection of Allogenic Umbilical Cord Mesenchymal Stem Cells"

Main outcome variables

Time taken until Union; Rate of union; Rate of Improvement in Pain and Function; Rate of Improvement in Hip, Knee and Ankle Range of Motion; Rate of Surgical

Complications; and Satisfaction with Surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221009056121N2**

Registration date: **2022-12-13, 1401/09/22**

Registration timing: **prospective**

Last update: **2022-12-13, 1401/09/22**

Update count: **0**

Registration date

2022-12-13, 1401/09/22

Registrant information

Name

Ehsan Najafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2267 4390

Email address

ehsan.n.6384@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Results of Tibial or Femoral Non-union Treatment with Two Methods "Internal Fixation + Autologous Bone Graft" and "Internal Fixation + Allogenic Umbilical Cord Mesenchymal Stem Cells"

Public title

Comparison of the Effect of Stem Cells and Bone Grafting in the Treatment of Thigh or leg Bone Non-union

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having Tibial or Femoral Non-union At Least 3 Months Between Fracture and Surgical Treatment Consent of the Patient to Participate in the Study

Exclusion criteria:

Previous Surgery on the Thigh or Leg Hip, Knee or Ankle Osteoarthritis Presence of Accompanying Injury in Thigh or Leg

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Not randomized

Randomization description**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 Tehran University of Medical Sciences

Street address

Department of Orthopedics, Dr. Shariati Hospital, Jalal Al Ahmad Highway

City

Tehran

Province

Tehran

Postal code

1411713135

Approval date

2022-06-14, 1401/03/24

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.285

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

Tibial Non-union

ICD-10 code

S82.209K

ICD-10 code description

Unspecified fracture of shaft of unspecified tibia, subsequent encounter for closed fracture with nonunion

2**Description of health condition studied**

Femoral Non-union

ICD-10 code

S72.309K

ICD-10 code description

Unspecified fracture of shaft of unspecified femur, subsequent encounter for closed fracture with nonunion

Primary outcomes**1****Description**

Union of Tibial Bone

Timepoint

3, 6, 9, 12, 24, 48 and 96 Months After Surgery

Method of measurement

Antero-posterior and Lateral Radiography of the Leg

2**Description**

Union of Femoral Bone

Timepoint

3, 6, 9, 12, 24, 48 and 96 Months After Surgery

Method of measurement

Antero-posterior and Lateral Radiography of the Thigh

Secondary outcomes**1****Description**

Pain

Timepoint

3, 6, 9, 12, 24, 48 and 96 Months After Surgery

Method of measurement

Visual Analogue Scale

2

Description

Function

Timepoint

3, 6, 9, 12, 24, 48 and 96 Months After Surgery

Method of measurement

Ask the Patient

3

Description

Time to Union

Timepoint

3, 6, 9, 12, 24, 48 and 96 Months After Surgery

Method of measurement

Week

4

Description

Hip Range of Motion

Timepoint

3, 6, 9, 12, 24, 48 and 96 Months After Surgery

Method of measurement

Clinical Examination (Degree)

5

Description

Knee Range of Motion

Timepoint

3, 6, 9, 12, 24, 48 and 96 Months After Surgery

Method of measurement

Clinical Examination (Degree)

6

Description

Ankle Range of Motion

Timepoint

3, 6, 9, 12, 24, 48 and 96 Months After Surgery

Method of measurement

Clinical Examination (Degree)

7

Description

Surgical Complications

Timepoint

3, 6, 9, 12, 24, 48 and 96 Months After Surgery

Method of measurement

Clinical Examination

8

Description

Satisfaction with Surgery

Timepoint

3, 6, 9, 12, 24, 48 and 96 Months After Surgery

Method of measurement

Ask the Patient

Intervention groups

1

Description

Intervention group: Nonunion of the Tibial or Femoral Bone undergoes Internal Fixation and Allogeneic Mesenchymal Stem Cells of Umbilical Cord Origin Implanted in Fibrin Gel are used to induce Union

Category

Treatment - Surgery

2

Description

Control group: Nonunion of the Tibial or Femoral Bone undergoes Internal Fixation and Autologous Cancellous Bone Graft are used to induce Union

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Shariati Hospital

Full name of responsible person

Mohammad Hosein Nabian

Street address

Department of Orthopedics, Dr. Shariati Hospital, Jalal Al Ahmad Highway

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Province

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1411713135

Phone

+98 21 8490 1000

Email

mh-nabian@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Hosein Nabian

Street address

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Ehsan Najafi

Position

Non-faculty Specialist Doctor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

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

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Hosein Nabian

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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

Tehran University of Medical Sciences

Full name of responsible person

Ehsan Najafi

Position

Non-faculty Specialist Doctor

Latest degree

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Other areas of specialty/work

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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