Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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 of 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 of 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 of 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 of 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
City
Tehran
Province
Tehran
Postal code
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
Department of Orthopedics, Dr. Shariati Hospital, Jalal Al Ahmad Highway
City
Tehran
Province
Tehran
Postal code
1411713135

Phone
+98 21 8490 1000
Email
mh-nabian@sina.tums.ac.ir
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
Street address
Department of Orthopedics, Dr. Shariati Hospital, Jalal Al Ahmad Highway
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Email
ehsan.n.6384@gmail.com

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
Orthopedics
Street address
Department of Orthopedics, Dr. Shariati Hospital, Jalal Al Ahmad Highway
City
Tehran
Province
Tehran
Postal code
1411713135
Phone
+98 21 8490 1000
Email
mh-nabian@sina.tums.ac.ir

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
Specialist
Other areas of specialty/work
Orthopedics
Street address
Department of Orthopedics, Dr. Shariati Hospital, Jalal Al Ahmad Highway
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Province
Tehran
Postal code
1411713135
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ehsan.n.6384@gmail.com

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