Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effectiveness of injection of mesenchymal stem cells' exosome in the treatment of bone non-union

Protocol summary

Study aim
Investigating the effectiveness of stem cell-derived exosomes in bone repair

Design
The present study is a quasi-experimental before-and-after study without a control group that will be conducted on 10 patients who refer to the orthopedic clinic of Imam Khomeini Hospital in Sari city with nonunion problems. This study is open Labell and without a control group.

Settings and conduct
in the operating room of Imam Khomeini hospital in Sari city, after prep and drape, under sterile conditions under C-arm, first aspiration of the area secretion for culture is performed and then exosome injection is performed. After exosome injection, one cc of hyaluronic acid will be injected to maintain this substance in place. Finally, the patient is treated with antibiotic prophylaxis (cephalexin 500 capsules every 6 hours) for three days. The injection site is examined for inflammatory reaction on the third day and a week after the injection. The patient will be followed up for six months and during this period, radiographs will be performed four times at 45-day intervals to determine the progress of the union. Finally, after the injection, patients will be followed up for six months and during this period, radiographs will be performed four times (at 45-day intervals) to determine the progress of the union.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with non-union in long bone fractures after 6 months Exclusion criteria: Patients with corticosteroids and a history of immunodeficiency and diabetes

Intervention groups
1 cc of exosomes containing 200 micrograms of total protein is injected into the fracture site.

Main outcome variables
Callus formation at the fracture site

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210228050535N4**
Registration date: **2025-04-28, 1404/02/08**
Registration timing: **prospective**

Last update: **2025-04-28, 1404/02/08**
Update count: **0**

Registration date
2025-04-28, 1404/02/08

Registrant information

Name
Amirali Khodashenas limoni

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-05, 1404/02/15

Expected recruitment end date
2025-08-25, 1404/06/03

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

The effectiveness of injection of mesenchymal stem cells' exosome in the treatment of bone non-union

Public title
The treatment of bone non-union by exosome therapy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with nonunion, long bone fractures after proper fixation Patients who have fracture site degradation visible on radiographs and tenderness at the fracture site, evidence of which persists 6 months after appropriate surgical fixation, indicating nonunion of the fracture. Patients with nonunion who have had more than one surgery and fixation
Exclusion criteria:
Unwillingness to participate in the study Use of corticosteroids History of immunodeficiency and diabetes from the study
Age
No age limit
Gender
Both

Phase
1
Groups that have been masked
No information
Sample size
Target sample size: **10**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Imam Hospital-Mazandaran University of Medical Sciences
Street address
Amir Mazandarani St
City
Sari
Province
Mazandaran
Postal code
4816633131
Approval date
2024-11-27, 1403/09/07
Ethics committee reference number
IR.MAZUMS.IMAMHOSPITAL.REC.1403.061

Health conditions studied

1

Description of health condition studied
Nonunion of fracture
ICD-10 code
M84.1
ICD-10 code description
Nonunion of fracture

Primary outcomes

1

Description
callus formation
Timepoint
1 month after injection
Method of measurement
radiography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the operating room after prep and drape, under sterile conditions under C-arm, first aspiration of the area secretion for culture is performed and then exosome injection is performed. After exosome injection, one cc of hyaluronic acid will be injected to maintain this substance in place. Finally, the patient is treated with antibiotic prophylaxis (cephalexin 500 capsules every 6 hours) for three days. The injection site is examined for inflammatory reaction on the third day and a week after the injection. The patient will be followed up for six months and during this period, radiographs will be performed four times at 45-day intervals to determine the progress of the union. Finally, after the injection, patients will be followed up for six months and during this period, radiographs will be performed four times (at 45-day intervals) to determine the progress of the union.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
imam khomaini hospital
Full name of responsible person
Masoud shayasteh azar
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mazandaran University of Medical Sciences
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University of Medical sciences Moallem square,Sari.Iran.
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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
Mazandaran 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
Mazandaran University of Medical Sciences
Full name of responsible person
Shabanali Khodashenas limoni
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Medical Biotechnology
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Other areas of specialty/work

Medical Biotechnology

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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