Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigation effects and safety of collagen scaffold reinforced with polyglycolic acid and mesenchymal stem cells harvested from the iliac crest in comparison with the iliac bone graft on the healing process of scaphoid fractures in young male patients (20 to 30 years)

Protocol summary

Study aim
The aim of the present study was to investigate the effects of collagen / poly glycolic acid scaffolds in combination with bone marrow autologous mesenchymal stem cells on bone repair in patients with orthopedic disorders such as nonunion and delayed union bone

Design
Clinical trial with intervention group, community-based and pragmatic, with parallel group design, non-blind, non-random

Settings and conduct
Collagen scaffold with polyglycolic acid fiber seeded by autologous bone marrow stem cells were implanted at the non-union site and its regenerative effects are investigated. Ten patients participate in the study (5 people in control group and 5 person in intervention group). Location of study: Department of Orthopedics, Imam Reza Hospital, Mashhad, Iran

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Every patient with non union fracture in the scaphoide bone; Age between 18- 60 years old; No infection in site of surgery; Be able and willing to participate in the study; Written informed consent; Non inclusion criteria: Evidence of malignancy; Pregnancy or breastfeeding; Patient by positive serology or PCR for HIV; hepatitis B or C infection; the patient with accompanied fracture such as hip fracture that could not bear weight

Intervention groups
Intervention group: Use of collagen scaffold with glycolic acid fibers and bone marrow stem cell. Control group: Use of bone graft from iliac crest (current standard method of non-union treatment)

Main outcome variables
The rate of bone formation; The rate of callus tissue formation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181222042074N1**
Registration date: **2020-09-03, 1399/06/13**
Registration timing: **retrospective**

Last update: **2020-09-03, 1399/06/13**
Update count: **0**

Registration date
2020-09-03, 1399/06/13

Registrant information

Name
Shirin Toosi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-06, 1398/01/17

Expected recruitment end date
2019-09-08, 1398/06/17

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigation effects and safety of collagen scaffold reinforced with polyglycolic acid and mesenchymal stem cells harvested from the iliac crest in comparison with the iliac bone graft on the healing process of scaphoid fractures in young male patients (20 to 30 years)

Public title
Repair of bone fractures with scaffold and stem cells
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with non-union fractures in Scaphoid bone Age between 18 and 60 years old No infection at the fracture site Patient availability for postoperative examinations Fill conscious awareness Individuals who want to refer for postoperative follow-up
Exclusion criteria:
Patients with other diseases, such as cancer. Patients with other associated motor injuries preventing normal ability. patients with infectious non-union fracture. Pregnant patients Patients have a positive HIV-positive serology or hepatitis B and C.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **10**
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
The Ethics committee of vice chancellor of research Mashhad University of Medical Sciences
Street address
Central building of Mashhad University of Medical Sciences (Qoreishi), Daneshgah street
City
Mashhad
Province
Razavi Khorasan
Postal code
9183773193
Approval date
2017-04-16, 1396/01/27
Ethics committee reference number
IR.MUMS.SP.1396.124

Health conditions studied

1

Description of health condition studied
non-union scaphoid fracture
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
The rate of bone formation
Timepoint
Before the intervention and 1, 3 and 6 months after surgery
Method of measurement
1-Quick DASH, PRWE, Wrist Mayo Clinic 2- Flexion, Extension, Supination, Pronation, Ulnar & radial deviations 3- CT scan before and after surgery 4- Radiography

2

Description
The rate of callus tissue formation
Timepoint
Before the intervention and 1, 3 and 6 months after surgery
Method of measurement
Radiographs and CT scans

Secondary outcomes

1

Description
Time duration of union
Timepoint
2 weeks, 3 months and 6 months after intervention
Method of measurement
Days, X-ray, physical examination

2

Description
Nonunion
Timepoint

6 months after intervention

Method of measurement

X-Ray, physical examination

3

Description

Surgical site infection

Timepoint

2 days, 2 weeks, 3 months after intervention

Method of measurement

physical examination, ESR and CRP lab tests

4

Description

duration of anesthesia

Timepoint

at the time of operation in operating room

Method of measurement

inspection

5

Description

pain

Timepoint

before, 3 and 6 months after surgery

Method of measurement

Visual Analog Scale (VAS)

6

Description

Function

Timepoint

before, 3 and 6 months after surgery

Method of measurement

Lower Extremity Functional Score (LEFS)

Intervention groups

1

Description

The control group: gets standard treatment with placement of iliac bone graft in site of non-union.

Category

Treatment - Devices

2

Description

Intervention group: Collagen / Polyglycolic acid scaffold with a weight ratio of 0.5 prepare. Bone marrow aspiration from the iliac crest is performed with a Jamshidi needle under local anesthesia, and the mesenchymal stem cells (MSCs) taken from each individual are transferred to a laboratory and cultured in the clean room. The cell will be used in passage 1, then MSCs seed into sponge and will be placed during surgery into scaphoid fracture. The healing process is assessed 1,3 and 6 months after surgery.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Mashhad, Imam Reza hospital

Full name of responsible person

Javad Behravan

Street address

Imam Reza hospital, Imam Reza square

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Mashhad

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9188617871

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Mashhad University of Medical Sciences

Proportion provided by this source

66

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

Mashhad University of Medical Sciences

Full name of responsible person

Shirin Toosi

Position

Postdoc Student

Latest degree

Ph.D.

Other areas of specialty/work

Tissue Engineering

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Biotechnology Research Center, School of Pharmacy, Ferdowci University, Park Square, Mashhad, Iran

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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