

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 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
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Sponsors / Funding sources

1

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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

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Person responsible for general inquiries

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