

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 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)

##### Phone

+98 51 1843 2825

##### Email address

tusi1063@gmail.com

##### 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  
**City**  
Mashhad  
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Razavi Khorasan  
**Postal code**  
9188617871  
**Phone**  
+98 51 3882 3255  
**Email**  
Tusi1063@gmail.com

## **Sponsors / Funding sources**

### 1

**Sponsor**  
**Name of organization / entity**  
Mashhad University of Medical Sciences  
**Full name of responsible person**  
Dr. Mohsen Tafaghodi  
**Street address**  
Central building of Mashhad University of Medical Sciences (Qoreishi), Daneshgah street  
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**Province**  
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+98 51 1841 1538  
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tafaghodim@mums.ac.ir  
**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

**Name of organization / entity**  
Mashhad University of Medical Sciences  
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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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## Person responsible for scientific inquiries

### Contact

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

### Contact

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Shirin Toosi  
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**Other areas of specialty/work**  
Pharmaceutical biotechnology  
**Street address**  
Biotechnology department; School of Pharmacy,  
Mashhad Medical University campus; Azadi square  
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Mashhad  
**Province**  
Razavi Khorasan  
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9188617871  
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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