

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 2026

### Comparison of the two methods of Augmented Plating and Exchange Nailing in the treatment of patients with long bones nonunion fractures

#### Protocol summary

##### Study aim

Comparison of Augmented Plating and Exchange Nailing Methods in Treating Patients with nonunion Long Bone fractures

##### Design

The two groups of patients who will be randomly assigned through close envelopes in order to undergo two different surgical treatment

##### Settings and conduct

All of the Patients with non-union of long bones will undergo surgery via either Augmented Plating or Exchange Nailing approach

##### Participants/Inclusion and exclusion criteria

Patients with nonunion long bone fractures

##### Intervention groups

Patients with non-union of long bone fractures who underwent either Exchange Nailing or Augmented Plating

##### Main outcome variables

Bone union duration Surgical complication Quality of life

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181216042007N1**

Registration date: **2019-09-01, 1398/06/10**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-09-01, 1398/06/10**

Update count: **0**

##### Registration date

2019-09-01, 1398/06/10

##### Registrant information

##### Name

Pooyan Jalalpour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4400 8273

##### Email address

p.jalalpour@sbmu.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-12-22, 1398/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the two methods of Augmented Plating and Exchange Nailing in the treatment of patients with long bones nonunion fractures

##### Public title

Comparison of different methods for treating long bones nonunion

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients with nonunion long bone fractures

##### Exclusion criteria:

Atrophic non unions Infected non-unions Pathologic fractures

##### Age

No age limit

##### Gender

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**

Target sample size: 80

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

closed envelope:In this method, for each patient, for the selection of the treatment method, the closed envelopes are equal and the total number of patients, which is written in half of the total envelopes, is one of two treatments, and each patient is asked to choose an envelope.and give it to the surgeon to choose the type of treatment without seeing the contents

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

Participants in the study and analyzer are unaware of how people are placed in the study groups

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

**Street address**

Shahid Arabi Avenue-next to Ayatollah Taleghani HospitaYemen Avenue\_Shahid Chamran Highway\_Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717443

**Approval date**

2018-12-01, 1397/09/10

**Ethics committee reference number**

IR.SBMU.MSP.REC.1397.816

**Health conditions studied**

1

**Description of health condition studied**

non union fractures

**ICD-10 code**

M84.1

**ICD-10 code description**

Nonunion of fracture

**Primary outcomes**

1

**Description**

Bone Union

**Timepoint**

45,60,120,240days after surgery

**Method of measurement**

Based on radiography and clinical conditions

**Secondary outcomes**

1

**Description**

quality of life

**Timepoint**

before surgery and 3&6months after surgery

**Method of measurement**

Visual Analogue Scale

2

**Description**

surgical complications

**Timepoint**

until three months after surgery

**Method of measurement**

surgeon's diagnosis

**Intervention groups**

1

**Description**

Intervention group: Patients who undergo surgery with the Augmented Plating method because of long bone non union fractures due to primary surgery.

**Category**

Treatment - Surgery

2

**Description**

Control group:Patients who undergo surgery with the Exchange Nailing method because of long bone non union fractures due to primary surgery.

**Category**

Treatment - Surgery

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Taleghani hospital

**Full name of responsible person**

Pooyan Jalalpour

**Street address**

Shahid Arabi Avenue-next to Ayatollah Taleghani  
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1985717443

**Phone**

+98 21 23871

**Fax**

**Email**

msh@smbu.ac.ir

**Web page address**

http://msh.smbu.ac.ir

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

**Street address**

velenjak st

**City**

tehran

**Province**

Tehran

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**Phone**

+98 21 23871

**Fax**

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**Email**

info@smbu.ac.ir

**Web page address**

https://www.smbu.ac.ir/

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Pooyan Jalalpour

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Orthopedics

**Street address**

Shahid Arabi Avenue-next to Ayatollah Taleghani  
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**Phone**

+98 21 2990 2233

**Email**

p.jalalpour@smbu.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Pooyan Jalalpour

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resident

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Pooyan Jalalpour

**Position**

resident

**Latest degree**

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**Other areas of specialty/work**

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**Email**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

collected for the primary outcome measure only

**When the data will become available and for how long**

starting 6 months after publication

**To whom data/document is available**

only available for people working in academic institutions  
if requested

**Under which criteria data/document could be used**

people working in orthopedic academic institutions

**From where data/document is obtainable**

email addresses

**What processes are involved for a request to access data/document**

After reviewing the condition of the applicant

**Comments**