Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

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

Protocol summary

Study aim
Comparison of Augmented Platting 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 envelops 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 Platting
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 Platting 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 Platting 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

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http://msp.sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

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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
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

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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