Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of the results of intramedullary nailing by static and dynamic methods in the erosion of femur and tibia shaft fractures.

Protocol summary

Study aim

Comparison of the result of intramedullary nailing by static and dynamic static methods in the corrosion weld of shaft fractures of femur and tibia bones.

Design

In the first group, nailing will be done by a static method and in the second group by a dynamic method. The sample size is 102 people, which will be assigned to one of these two groups using the block randomization method. The design of the study will be concurrent. The usual phases of the clinical trial are not applicable in this study. Also, the study will be conducted in a un blind manner.

Settings and conduct

This study will be conducted in Shahid Madani Hospital of Karaj. after obtaining informed consent from the eligible people, the people will be randomly divided into two groups of static and dynamic nailing. For this purpose, quadruple blocks (A, A, B, B) will be created and two groups of people will be formed in each block. These blocks will be created randomly so that in each group, the number of people in the study phase is almost equal. Therefore, at each stage of the study, a block was randomly selected and then people were assigned to the relevant group according to the order in which they appeared in that block. (A static nailing group, B dynamic nailing group).

Participants/Inclusion and exclusion criteria

Inclusion criteria:1-18 to 80 years old.2-Informed consent.3-Having a fracture of the transverse or short inclination type.4-The time to go to the hospital is less than two weeks after the fracture Exclusion criteria:1-Open fractures.2-Fractures with chopped parts.3-Fractures associated with neurovascular injuries.4-Fractures previously treated with intramedullary nailing or periprosthetic fractures.5-Diabetes.6-Osteoporosis

Intervention groups

1:static intramedullary nailing 2:dynamic intramedullary nailing

Main outcome variables

The end result of bone healing Duration of complete bone healing

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220201053910N1**
Registration date: **2022-07-04, 1401/04/13**
Registration timing: **registered_while_recruiting**

Last update: **2022-07-04, 1401/04/13**
Update count: **0**

Registration date

2022-07-04, 1401/04/13

Registrant information

Name
Ali Sedighi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 26 3440 3843
Email address
sedighiali112@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-09-06, 1401/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the results of intramedullary nailing by static and dynamic methods in the erosion of femur and tibia shaft fractures.

Public title

Comparison of the result of intramedullary nailing by static and dynamic methods

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

18 to 80 years old Informed consent Having a fracture of the transverse or short inclination type The time to go to the hospital is less than two weeks after the fracture

Exclusion criteria:

Open fractures Fractures with chopped parts Fractures associated with neurovascular injuries Fractures previously treated with IMN or periprosthetic fractures Diabetes Osteoporosis

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, after obtaining the informed consent of eligible individuals, individuals will be randomly divided into two groups: static and dynamic IMN. For this purpose, quadruple blocks (A, A, B, B) will be created and two groups of people will be formed in each block. These blocks are created randomly so that in each group, the number of people in the study stage is almost equal. Therefore, at each stage of the study, a block (allocation of four symbols inside the block is random and there are many blocks) is randomly selected and then people will assign to the relevant group in the order in which the block appears. (A group will be static IMN, B group will be dynamic IMN).

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

Ethics Committee of Alborz University of Medical Sciences

Street address

mahan blvd-shahid madani hospital-Clinical Research Development Unit

City

karaj

Province

Alborz

Postal code

۳۱۴۳۷۴۴۶۹۳

Approval date

2021-09-20, 1400/06/29

Ethics committee reference number

IR.abzums.rec.1400.234

Health conditions studied

1

Description of health condition studied

Fractures of the femoral shaft and tibia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The final result of welding based on clinical and radiological evaluation (Harper criteria)

Timepoint

Examinations will be done immediately after the surgery and then 8 weeks later and after that at intervals of 4 weeks to 6 months and the last visit and imaging will be done 9 to 21 months after the surgery.

Method of measurement

Patients in both groups will be regularly examined and visited and photographed in two views and profile of the fracture site.

2

Description

Duration of complete welding

Timepoint

Examinations will be done immediately after the surgery and then 8 weeks later and after that at intervals of 4 weeks to 6 months and the last visit and imaging will be done 9 to 21 months after the surgery.

Method of measurement

Patients in both groups will be regularly examined and visited and photographed in two views and profile of the fracture site.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group, the static intramedullary nailing method will be used to fix the fracture in such a way that 3 to 4 screws are used at both ends to prevent vertical and rotational instability and bending.
Category
Treatment - Devices

2

Description
Control group: In this group, the dynamic intramedullary nailing method will be used. In this way, a distal or proximal screw will be used that allows vertical pressure to control rotational instability and bending.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani Hospital, Karaj
Full name of responsible person
Ali Sedeghi
Street address
Mahan blvd-shahid madani hospital-Clinical Research Development Unit
City
Karaj
Province
Alborz
Postal code
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+98 26 3420 9028
Email
sedighiali112@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Ali Sedeghi
Street address
Mahan blvd-shahid madani hospital.Clinical Research Development Unit
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Email
sedighiali112@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Karaj 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
Karaj University of Medical Sciences
Full name of responsible person
Ali Sedighi
Position
Orthopedic Assistant
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
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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
1. Participants' data file will be shared after de-identifying individuals 2- The study protocol will be shared after the study 3- The statistical analysis map will be shared after the study 4- The informed consent form will be shared after the study 5- The statistical analysis map will be shared after the study 6. The clinical study report will be shared after the study 7. The codes used in the analysis will be shared after the study 8. The data classification system will be shared after the study
When the data will become available and for how long
The data access period will start 6 months after the publication of the study results
To whom data/document is available
All people working in the field of medical sciences will be allowed to access the data
Under which criteria data/document could be used
Medical researchers can use the results of this study to conduct medical research, provided that they follow the principles of such research, such as non-copying.
From where data/document is obtainable
Applicants can refer to the Clinical Research Development Unit of Madani Karaj Hospital at the address of Karaj, Mahan Blvd., Madani Hospital, Clinical Research Development Unit, to receive data. They can also email sedighiali112@gmail.com
What processes are involved for a request to access data/document
Applicants' request for data use will be reviewed by the Clinical Research Development Unit of the Civil Hospital and if this unit agrees, the data will be provided to the applicants.
Comments