

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of treatment results in suprapatellar and infrapatellar intramedullary nailing for tibial shaft fractures

Protocol summary

Study aim

Comparison of the results and complications of suprapatellar and infrapatellar methods in tibial nailing in patients with leg fracture

Design

Patients with conditions after entering the study are divided into two groups of suprapatellar intervention and infrapatellar control by Random number software. The groups of this study are parallel. According to statistical analysis, the sample size of this study is 112 patients. After grouping, patients undergo surgery and follow-up care.

Settings and conduct

This study is conducted at Hamadan University of Medical Sciences and Besat hospital, and after selecting the patients and grouping them, each group is subjected to the respective surgery after the surgery, multiple follow-ups are done for the patients on a weekly and monthly basis, and the relevant questionnaires are completed. All people related to the treatment of the patients except the surgical team and the patients themselves are blinded in this study.

Participants/Inclusion and exclusion criteria

Entry conditions include tibial trunk fracture. The conditions of non-entry include any problems in the IMN treatment in such a way that this method cannot be used, as well as the patients' lack of satisfaction.

Intervention groups

Intervention group 1: Supra patellar treatment.
Intervention group 2: Infrapatellar treatment.

Main outcome variables

Knee functional score; Knee pain score; Welding rate; Irritability; Duration of operation; The number of complications; Knee range of motion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220821055759N1**

Registration date: **2022-09-07, 1401/06/16**

Registration timing: **prospective**

Last update: **2022-09-07, 1401/06/16**

Update count: **0**

Registration date

2022-09-07, 1401/06/16

Registrant information

Name

Milad Alizadehhaghighi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 921 189 4019

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-21, 1401/06/30

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of treatment results in suprapatellar and infrapatellar intramedullary nailing for tibial shaft fractures

Public title

Treatment results in suprapatellar and infrapatellar intramedullary nailing for tibial shaft fractures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

shaft fracture of tibia

Exclusion criteria:

Failure to accept the patient or inability to use the IMN method for any other reason

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Randomized

Randomization description

The list of people with inclusion criteria is selected by random numbers using the Random number application in two separate lists with an equal number of men and women who undergo surgery.

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 Hamedan University of Medical Sciences

Street address

Shahid Fahmide boulevard

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7451814948

Approval date

2022-08-20, 1401/05/29

Ethics committee reference number

IR.UMSHA.REC.1401.464

Health conditions studied

1

Description of health condition studied

Tibial shaft fracture

ICD-10 code

S82.2

ICD-10 code description

Fracture of shaft of Tibia without Fibula

Primary outcomes

1

Description

Knee score in Lysholm knee score

Timepoint

6weeks, 3monthes, 6months, 1 year

Method of measurement

Lysholm knee score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Treatment with supra ptellar nailing

Category

Treatment - Surgery

2

Description

Control group: Treatment with infra ptellar nailing

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamedan Besat hospital

Full name of responsible person

Dr Sepehr Shiroee

Street address

Besat boulevard

City

Hamedan

Province

Hamadan

Postal code

7426359875

Phone

+98 81 3264 0020

Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

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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

Hamedan University of Medical Sciences

Proportion provided by this source

80

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**

Hamedan University of Medical Sciences

Full name of responsible person

Dr Sepehr Shirouei

Position

Assistant Professor

Latest degree

Specialist

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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

All the data after the individuals cannot be identified are recorded in the archive of the clinical studies center of Hamadan Ba'ath Hospital and can be presented to the relevant people to conduct other studies.

When the data will become available and for how long

It is possible to start accessing the data of this study 6 months after publication.

To whom data/document is available

Access is free for everyone

Under which criteria data/document could be used

There are no special conditions for using the data of this study

From where data/document is obtainable

Those interested can use this information by referring to the website of the journal in which the article was published

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

as soon as possible by referring to the journal website or comprehensive sites

Comments