

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

A clinical trial comparison of two methods of transpatellar and parapatellar for anterior knee pain after intramedullary nailing for patients with fractures of tibial shaft

Protocol summary

Summary

Objectives: Comparison of two methods of transpatellar and parapatellar for anterior knee pain after intramedullary nailing of fractures of tibial shaft. Design: patients with fractures of tibial shaft, two groups by method of transpatellar and parapatellar, 68 patients, single-blind, randomized, single-center, phase II trial. Setting and conduct: Nailing with method of transpatellar and nailing with method of parapatellar is placed randomly into two groups. Severity of pain is evaluated according to VAS criteria during one month and six month after surgery. Participants including major eligibility criteria: Inclusion criteria include patients undergoing fractures of tibial shaft for intramedullary nailing; exclusion criteria include lack of fractures of tibial shaft for intramedullary nailing. Intervention: Nailing with method of transpatellar in first intervention group and nailing with method of parapatellar in second intervention group. Main outcome measures variable: Severity of pain is evaluated according to criteria of VAS.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016020926474N1**
Registration date: **2016-03-26, 1395/01/07**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-26, 1395/01/07

Registrant information

Name

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Name of organization / entity

Ahvaz Jondishapour University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jondishapour University of Medical Sciences

Expected recruitment start date

2016-03-20, 1395/01/01

Expected recruitment end date

2016-05-21, 1395/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial comparison of two methods of transpatellar and parapatellar for anterior knee pain after intramedullary nailing for patients with fractures of tibial shaft

Public title

Comparison of two methods surgery of locking intramedullary nailing for tibial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients undergoing fractures of tibial shaft for intramedullary nailing; age more than 15 years; diaphyseal fracture of the tibia. Exclusion criteria: lack of

fractures of tibial shaft for intramedullary nailing; diabetic; safety defects; immunodeficiency; ulceration at the entry point nail; previous fractures and chronic pain in front knee before fracture.

Age

From **15 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Ahvaz Jondishapour University of Medical Sciences

Street address

Vice chancellor for research, Central of Ahvaz Jondishapour University of Medical Sciences, City of University

City

Ahvaz

Postal code

61357-15794

Approval date

2016-01-23, 1394/11/03

Ethics committee reference number

ir.ajums.rec.1394.585

Health conditions studied

1

Description of health condition studied

Fractures of Tibial Shaft

ICD-10 code

S82.2

ICD-10 code description

Fracture of shaft of tibia

Primary outcomes

1

Description

Pain after nail placement

Timepoint

1 month and 6 months after nail placement

Method of measurement

According to the VAS scale

Secondary outcomes

empty

Intervention groups

1

Description

Nailing by method of transpatellar

Category

Treatment - Surgery

2

Description

Nailing by method of parapatellar

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Akbar Sangari

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Sponsors / Funding sources

1

Sponsor

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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
Ahvaz Jondishapour University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty