Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 2026

Comparison of results and complications of two trans-patellar and minimally invasive approaches in intramedullary nailing procedure in tibial fractures

Protocol summary

Study aim

1) Determining and comparing the average pain at the surgical incision site and general pain in patients undergoing intramedullary nailing in the two groups of trans Patellar and minimally invasive approaches at 1, 3, 12 and 24 weeks after surgery 2) Determining and comparing the mean range of motion of the knee in patients undergoing intramedullary nailing in the two groups of trans Patellar and minimally invasive approaches at 1, 3, 12 and 24 weeks after surgery 3) Determining and comparing the frequency of knee hematoma in patients undergoing intramedullary nailing in two groups of trans Patellar and minimally invasive approaches at 1, 3, 12 and 24 weeks after surgery 4) Determining and comparing the average size of the tibial protrusion in the patients undergoing intramedullary nailing in the two groups of trans Patellar and minimally invasive after surgery

Design

Clinical trial with control group, with parallel groups, with blinded, randomized, on 122 patients. Excel software rand function was used for randomization.

Settings and conduct

The study was performed on patients with tibial fracture and hospitalized in Alzahra and Kashani hospitals of Isfahan by the orthopedic system of these hospitals. due to the incision site after surgery, it is not possible for the patient and the follow-up assistant to be blinded. But the one who does the statistical analysis is blind to assigning groups.

Participants/Inclusion and exclusion criteria

entry: 20-40 years Tibial fracture Not entry: Immunodeficiency Diabetes Malnutrition Multiple Trauma Dirty Wounds and Gastillo Type 3

Intervention groups

Evaluation of 2 surgical methods in tibial fracture

Main outcome variables

Determining the superiority of the selective approach to tibial Intramedullary nailing; Determining the complications of selective approaches in tibial intramedullary nailing.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201028049176N1**
Registration date: **2020-11-19, 1399/08/29**
Registration timing: **registered_while_recruiting**

Last update: **2020-11-19, 1399/08/29**
Update count: **0**

Registration date

2020-11-19, 1399/08/29

Registrant information

Name

hamid mehrabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3779 1559

Email address

hamidmehrabi67@resident.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-08, 1399/06/18

Expected recruitment end date

2020-12-08, 1399/09/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of results and complications of two trans-patellar and minimally invasive approaches in intramedullary nailing procedure in tibial fractures

Public title

Evaluation of 2 surgical methods in tibial fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Close or open fracture of tibia gastillo type 1 and 2 Indication of intermedullary nailing, which was determined by 2 professors Close reduction is done and fixation with intermedullary nail

Exclusion criteria:

Immunodeficiency Diabetes Malnutrition with albumin below 3.5 and BMI less than 18 multiple trauma Dirty Gastillo Type 3 Wounds

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **122**

Randomization (investigator's opinion)

Randomized

Randomization description

According to the random code provided by the software to the executor of the project and printed on a sheet and in sealed envelopes, the patient number is assigned to him.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the fact that the incision site is visible after surgery, it is not possible for the patient and the follow-up assistant to blind. But the one who does the statistical analysis is blind to assigning groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Unit 4, 6-unit apartment, South side of the park, Yarmohammadian Alley, Allameh Jafari St, Rudaki Street

City

Isfahan

Province

Isfehan

Postal code

8176963935

Approval date

2020-09-07, 1399/06/17

Ethics committee reference number

IR.MUI.MED.REC.1399.461

Health conditions studied

1

Description of health condition studied

tibial fracture

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Incisional pain and general postoperative pain and restricted postoperative knee movement and postoperative knee hematoma

Timepoint

Evaluation of pain and hematoma and restriction of knee movement at 1, 3, 12 and 24 weeks after surgery

Method of measurement

Visual Analogue Scale; physical examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Minimally invasive surgical approach to intramedullary nailing in tibial fractures

Category

Treatment - Surgery

2

Description
Control group: Parapatellar surgical approach to intramedullary nailing in tibial fractures
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra and Kashani hospital
Full name of responsible person
Hamid mehrabi
Street address
Unit 4, 6-unit apartment, South side of the park, Yarmohammadian Alley, Allameh Jafari St, Rudaki Street
City
Isfahan
Province
Isfehan
Postal code
8176963935
Phone
+98 31 3779 1559
Email
hamidmehrabi67@resident.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Hamid mehrabi
Street address
Unit 4, 6-unit apartment, South side of the park, Yarmohammadian Alley, Allameh Jafari St, Rudaki Street
City
Isfahan
Province
Isfehan
Postal code
8176963935
Phone
+98 31 3779 1559
Email
hamidmehrabi67@resident.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Hamid mehrabi
Position
Assistant
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
Unit 4, 6-unit apartment, South side of the park, Yarmohammadian Alley, Allameh Jafari St, Rudaki Street
City
Isfahan
Province
Isfehan
Postal code
8176963935
Phone
+98 31 3779 1559
Email
hamidmehrabi67@resident.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Hamid mehrabi
Position
Assistant
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
Unit 4, 6-unit apartment, South side of the park, Yarmohammadian Alley, Allameh Jafari St, Rudaki Street
City
Isfahan
Province
Isfehan

Postal code
8176963935
Phone
+98 31 3779 1559
Email
hamidmehrabi67@resident.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Hamid mehrabi
Position
Assistant
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
خ رودکی خ علامه جعفری کوی یارمحمدیان ضلع جنوبی پارک آپارتمان 6 واحدی واحد 4
City
Isfahan
Province
Isfehan
Postal code
8176963935
Phone
+98 31 3779 1559
Email
hamidmehrabi67@resident.mui.ac.ir

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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data is potentially shareable after unidentified individuals
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
In order to expand studies and improve patients' health
From where data/document is obtainable
hamidmehrabi67@resident.mui.ac.ir
What processes are involved for a request to access data/document
Reason for request and data requested
Comments