

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of Accuracy and Cost-benefit (cost-effectiveness) of Fluoroscopy-guided Surgical Navigation in Distal Locking of Intramedullary Nails, Compared to the Conventional Method

Protocol summary

Study aim

Determining the accuracy and cost-effectiveness of using surgical guidance system with the help of fluoroscopic images is to place the distal locking screws of intramedullary nails in comparison with the conventional method.

Design

The study will be performed in two groups of control and intervention group as double blinded and randomized through random numbers using Excel. The sample size in this study is 44 patients.

Settings and conduct

This clinical trial project is being carried out using the C-Guide system, a product of Parsis Company and performed in Shariati Hospital. This study is double blinded in which patients and the person in charge of data analysis are not aware. In Parsis surgical guidance system, images are analyzed and calibration processes are performed. The doctor will then be able to see the direction of his instrument on the images.

Participants/Inclusion and exclusion criteria

Patients with diaphysis fractures of the lower limb bones (femoral shaft or tibia) who are candidates for intramedullary nails (IMN) implantation. Exclusion criteria are as follows: Patients with open femoral or tibial shaft fractures, patients with small canal diameter, patients with bone canal obstruction, patients with a history of infection or active bone canal infection

Intervention groups

The intervention group are patients who will be placed under the distal screw of the femoral or tibial concussion using the tracking method using surgical navigation or fluoroscopy. The control group includes patients in whom the implantation of the distal femoral or tibial conchae screw will be determined using the conventional method (Conventional C-arm).

Main outcome variables

Duration of screw installation
Duration of operation
Received radiation
Total irradiation time
Repeat shooting
Number of drills
Check the alignment of screws by imaging
Duration of presence in the operating room
Setup time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210712051854N6**
Registration date: **2023-01-04, 1401/10/14**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-04, 1401/10/14**

Update count: **0**

Registration date

2023-01-04, 1401/10/14

Registrant information

Name

Mohammad Hossein Nabian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Accuracy and Cost-benefit (cost-effectiveness) of Fluoroscopy-guided Surgical Navigation in Distal Locking of Intramedullary Nails, Compared to the Conventional Method

Public title

Evaluation of the Effect of Surgical Navigation System on Diaphysis Fractures of Long Lower Limb Bones

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with diaphysis fractures of the long bones of the lower extremities (femoral shaft or tibia) who are candidates for intramedullary nails (IMN) implantation.

Exclusion criteria:

Patients with open femoral or tibial shaft fractures
patients with small canal diameter patients with bone canal obstruction patients with a history of infection or active bone canal infection

AgeFrom **18 years** old to **65 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample sizeTarget sample size: **44****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients will be randomly divided into control and intervention groups. The randomization of people will be done using the Permuted block randomization method with the random selection of the size of the blocks. Block randomization works by randomizing participants within blocks such that an equal number is assigned to each treatment. For example, given a block size of 4, there are six possible ways to equally assign participants to a block. Allocation proceeds by randomly selecting one of the orderings and assigning the next block of participants to study groups according to the specified sequence. Furthermore, the block size must be divisible by the number of study groups. A disadvantage of block randomization is that the allocation of participants may be predictable and result in selection bias when the study groups are unmasked. That is, the treatment assignment that has so far occurred least often in the block likely will be the next chosen. Selection bias may be reduced by using random block sizes and keeping the

investigator blind to the size of each block.

Blinding (investigator's opinion)

Double blinded

Blinding description

The blinding method in this study is double-blinded, in which the patients, the person responsible for randomization, and the person responsible for data analysis are not aware of the randomization setting of the study. Patients, the person responsible for randomization, and the person responsible for data analysis will only be aware of each person belonging to one of the group's A and B. They will not know which of the intervention or control groups each of the two groups, A and B, represents. Unlike the above people, the surgical team will know which of the intervention or control groups each of groups A and B belongs to.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of School of Medicine-
Tehran University of Medical Sciences

Street address

Floor 13, Block A, Ministry of Health & Medical
Education Headquarters, Between Zarafshan &
South Falamak, Qods Town

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Province

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Postal code

1419943471

Approval date

2022-04-05, 1401/01/16

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.010

Health conditions studied**1****Description of health condition studied**

Diaphysis fracture of the long bones of the lower
extremities (Femoral Shaft)

ICD-10 code

S72.3

ICD-10 code description

Fracture of shaft of femur

2

Description of health condition studied

Diaphysis fracture of the long bones of the lower extremities (Tibia)

ICD-10 code

S82.20

ICD-10 code description

Unspecified fracture of shaft of tibia

Primary outcomes

1

Description

Screw insertion time

Timepoint

From the time of the start of the distal screw insertion until the end of it, during the operation

Method of measurement

Based on the time measured by the stopwatch

2

Description

Duration of operation

Timepoint

From the time of the first fluoroscopic image of the organ to the time of preparing the fluoroscopic image for the final check

Method of measurement

Based on the time measured by the stopwatch

3

Description

Radiation dose received

Timepoint

The amount of radiation received during the operation

Method of measurement

With the help of special radiology badges

4

Description

X-ray radiation time

Timepoint

The duration of taking pictures with the C arm in each of the imaging methods

Method of measurement

Using the device's own settings

5

Description

The number of repetitions of photography

Timepoint

The number of times of taking pictures with the arm in each of the imaging methods

Method of measurement

Using the device's own settings

6

Description

The number of times to drill

Timepoint

The number of times to drill to find the screw path

Method of measurement

The number of times the guide contour leaves, which is mentioned in the patient's file and recorded by the resident during the procedure

7

Description

Duration of operating room stay

Timepoint

The duration of the patient's presence in the operation room from the time of entry to the time of exit

Method of measurement

Based on the time measured by the stopwatch

8

Description

Setup time

Timepoint

The time required to set up the operation equipment

Method of measurement

Based on the time measured by the stopwatch

Secondary outcomes

1

Description

Checking the alignment of screws by imaging

Timepoint

Checking the alignment of the distal screws with respect to the contour in the post-operative graph - the presence or absence of angulation and torsion

Method of measurement

Based on the opinion of an orthopedic and radiology specialist

2

Description

Duration of anesthesia

Timepoint

From the time of induction of anesthesia until the time of complete return of consciousness

Method of measurement

Based on the time measured by the stopwatch

3

Description

Checking the amount of union

Timepoint

In time intervals of 3, 6, 9 and 12 months after surgery

Method of measurement

Based on imaging data and the opinion of an orthopedic specialist

Intervention groups

1

Description

Intervention group: There are patients who will have a distal femoral or tibial concave screw implantation using surgical navigation or fluoroscopy. In this method, the navigation system is calibrated using radiographic images prepared before the operation. The navigation system is then calibrated with the patient in another step during the surgery. Distal IMN screw implantation in these patients is determined based on the location determined by the navigation system using imaging and anatomical landmarks of the patient.

Category

Treatment - Surgery

2

Description

Control group: Includes patients in whom the distal femoral or tibial IMN screw implantation will be determined using the conventional method (Conventional C-arm). In this method, for implanting the distal cone screw, an inter-operative radiograph will be taken from the bone by C-arm. Based on that, screw implantation is done. After each screw implantation, radiography of the bone will be done again by C-arm to ensure the correctness of the screw insertion. If the distal screw is not inserted correctly, this process will be repeated and will continue until the correctness of the distal screw is ensured.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital

Full name of responsible person

Mohammad Hossein Nabian

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North Kargar St., Jalal Al-Ahmad Three Ways,
Opposite the Faculty of Economics, Dr. Shariati
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Vice Chancellor for Research and Technology, Sixth
Floor, Central Organization of Tehran University of
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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

Tehran University of Medical Sciences

Proportion provided by this source

15

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

2

Sponsor

Name of organization / entity

Parseh Intelligent Surgical Systems Co.

Full name of responsible person

Mustafa Abdul Ghafar

Street address

No. 8, Hamedan Aly, North Kargar St, Tehran, Iran

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contact@parsiss.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Parseh Intelligent Surgical Systems Co.

Proportion provided by this source

85

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hossein Nabian

Position

Associated Professor

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

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Position

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Person responsible for updating data

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable