Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Evaluation of Accuracy and Cost-benefit (cost-effectivness) of Flouroscopy-guided Surgical Navigation in Distal Locking of Intramedulary 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)

Phone

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Email address

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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-effectivness) of Flouroscopy-guided Surgical Navigation in Distal Locking of Intramedulary 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
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target 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 Zarafashan & South Falamak, Qods Town
City
Tehran
Province
Tehran
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 Research and Treatment Center

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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 Medical Sciences, Ghods St., Keshavarz Blvd.

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vcr@tums.ac.ir

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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1418693914

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+98 21 6612 4395

Email

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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Latest degree

Subspecialist

Other areas of specialty/work

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Position

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Latest degree

Subspecialist

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