

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison proximal femoral nailing (PFN) versus dynamic hip screw(DHS) in intertrochanteric fracture

Protocol summary

Study aim

Comparison proximal femoral nailing (PFN) versus dynamic hip screw(DHS) in intertrochanteric fracture

Design

This study clinical trial and double blind.36 patients with fetal intertrochanteric fractures who were referred to Valiasr Hospital were admitted to the study.

Settings and conduct

This study clinical trial and double blind.36 patients with fetal intertrochanteric fractures who were referred to Valiasr Hospital were admitted to the study.We divide patients in two groups randomly.Randomized allocation in clinical trial studies refers to the process of dividing participants into different groups randomly. Randomizing gives each participant equal odds for being placed in each of the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Intertrochantric fracture, aged 18 years and older, both gender, fracture less than 2 weeks, lack of multiple fractures, the absence of pathologic fracture, lack of Background Bone Disease Exclusion criteria: lack of cooperation, fractures in children

Intervention groups

We surgery proximal femoral nailing (PFN) intertrochanteric fracture in first group and we surgery dynamic hip screw(DHS) in intertrochanteric fracture in second group.

Main outcome variables

Wound healing clinically, Improvement of fracture by radiological examination

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N80**

Registration date: **2018-06-11, 1397/03/21**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-11, 1397/03/21**

Update count: **0**

Registration date

2018-06-11, 1397/03/21

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 86 3222 2003

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-01, 1396/12/10

Expected recruitment end date

2020-02-29, 1398/12/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison proximal femoral nailing (PFN) versus dynamic hip screw(DHS) in intertrochanteric fracture

Public title

Comparison proximal femoral nailing (PFN) versus dynamic hip screw(DHS) in intertrochanteric fracture

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Intertrochantric fracture Aged 18 years and older both gender Fracture less than 2 weeks Lack of multiple fractures The absence of pathologic fracture Lack of Background Bone Disease

Exclusion criteria:
Lack of cooperation Fractures in children

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple individual randomization with random number in division of groups in two groups A and B. Randomized patients are divided into two groups. Randomized allocation in clinical trial studies refers to the process of dividing participants into different groups randomly. Randomizing gives each participant equal odds for being placed in each of the groups. The candidate patients who enter the study are randomly assigned to the randomly assigned table of randomly assigned to the two groups. Individual

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is clinical trial. Outcome evaluator and analyzer are blind (double blind). Outcome evaluator and analyzer don't aware from grouping. Patients and surgeons are aware of the grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome evaluator, and the surgeon is the real grouping

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Arak University Of Medical Sciences

Street address

Vice chancellor for research, Payambar azam

complex, Basij square, Sardasht, Arak

City
Arak

Province
Markazi

Postal code
3814957558

Approval date
2018-02-26, 1396/12/07

Ethics committee reference number
IR.ARAKMU.REC.1396.291

Health conditions studied

1

Description of health condition studied

intertrochanteric fracture femur

ICD-10 code

S72.14

ICD-10 code description

Intertrochanteric fracture of femur

Primary outcomes

1

Description

Wound healing

Timepoint

2, 5 and 15 day after surgery

Method of measurement

clinical observation

2

Description

Fracture improvement

Timepoint

15 days, one month, 3 months , 6 months and 12 months after surgery

Method of measurement

Radiological examination

3

Description

Lower limb movement

Timepoint

2, 5 and 15 day after surgery

Method of measurement

Harris hip score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We surgery proximal femoral nailing (PFN) intertrochanteric fracture. In this method, by opening the channel entrance in the central part, the fracture is fixed by manipulating the channel from the channel center into the fracture section. The fracture is kept in the depressed state

Category

Treatment - Surgery

2

Description

Intervention group: we surgery dynamic hip screw (DHS) in intertrochanteric fracture. In this method, after opening the site of operation on the DHS bed through the lateral incision, the location Determine the fracture and then set it up using proper traction and maneuver and after assurance DHS controls it with radiography in the operating room.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr hospital

Full name of responsible person

Dr Amirhossein Moradi

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak 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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Dr Amirhossein Moradi

Position

Assistant professor
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Orthopedics
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Person responsible for updating data

Contact
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Full name of responsible person
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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

When we publish article in journal.

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Amirhossein Moradi

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

They have to write letters to the professors and the university.

Comments