

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

Comparison of the effect of proximal femoral nailing (PFN) and dynamic hip screwing (DHS) on mortality and Harris hip score of patients with intertrochanteric fracture.

Protocol summary

Study aim

Investigating and comparing mortality and Harris Hip Score grading in patients with intertrochanteric fractures treated with nailing from the proximal femur and patients treated with dynamic femoral screwing

Design

A clinical trial, parallel-group, single-blind, block-randomized, 206 patients, using the website www.sealedenveloppe.com. for randomization.

Settings and conduct

Valie-asr hospital

Participants/Inclusion and exclusion criteria

Inclusion criteria: Introcentric fracture; Age 50 years and above; Both genders; Fracture duration less than 2 weeks. Exclusion criteria: multiple fractures; pathological fracture

Intervention groups

. One group will undergo PFN surgery. In this method, by opening the entrance of the canal in the central part, the fracture is manipulated and the guide is inserted from the center of the canal into the fractured part. The fracture is kept in place. And the second group is operated with DHS. In this method, after opening the operation site on the DHS bed through a lateral incision, the location of the fracture is determined, and then positioning is done using appropriate traction and maneuvers, and after ensuring its control with radiography, the DHS is placed in the operating room.

Main outcome variables

Mortality rate, Harris hip score (HHS)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190810044492N2**

Registration date: **2023-07-31, 1402/05/09**

Registration timing: **prospective**

Last update: **2023-07-31, 1402/05/09**

Update count: **0**

Registration date

2023-07-31, 1402/05/09

Registrant information

Name

Mitra Jaras

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3506

Email address

m.jaras@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-06-21, 1403/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of proximal femoral nailing (PFN) and dynamic hip screwing (DHS) on mortality and Harris hip score of patients with intertrochanteric fracture.

Public title

Comparison of the effect of proximal femoral nailing (PFN) and dynamic hip screwing (DHS) in patients with intertrochanteric fractures.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Introcentric fracture Age 50 years Both genders Fracture duration less than 2 weeks

Exclusion criteria:

Lack of willingness to participate History of multiple fractures History of pathological fracture History of underlying bone disease

Age

From 50 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: 206

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the block randomization method will be used. The randomization unit is the person. And they are divided into two groups based on the block randomization method in formats 4 and 8. For better randomization, web-based software will be used to prepare a randomization list, which creates random permutations for both types of treatment in each block. And due to the change of permutations in each block, concealment is also observed and during the implementation of the study, the predictability of the treatment for each patient is reduced by the researcher. The site used for random permutation block method: <https://www.sealedenvelope.com/simple-randomiser/v1/lists>

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the double-blindness of the study, the data collector knows about the groupings, but the patients and the analyst do not know about the groupings. Informed consent is obtained from the patient that one of the proximal femoral nailing (PFN) and dynamic hip screwing (DHS) surgical procedures will be performed, but the patient will not know the type of surgical technique. The analyst is also a statistician who is outside the intervention process.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Basij Ave, Chamran Blvd, Arak Town

City

Arak

Province

Markazi

Postal code

۳۸۱۹۶۹۳۴۰

Approval date

2023-02-01, 1401/11/12

Ethics committee reference number

IR.ARAKMU.REC.1402.004

Health conditions studied

1

Description of health condition studied

Intertrochanteric Fracture

ICD-10 code

S72.14

ICD-10 code description

Intertrochanteric fracture of femur

Primary outcomes

1

Description

Mortality

Timepoint

1, 3 and 6 months after surgery

Method of measurement

Follow up

2

Description

Harris hip score assessment (HHS)

Timepoint

1, 3 and 6 months after surgery

Method of measurement

Demographic characteristics checklist and Harris hip score (HHHS). HHS is a scoring index of the hip joint that has 100 points, and the higher the score, the more successful the surgery is, and it consists of four subscales: pain (44 points), Function (47 points), deformity (4 points) and range of motion (5 points). Pain range measures the intensity of pain, its effect on activities and the need for pain medication.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: One group will undergo PFN (proximal femoral nailing)surgery. In this method, by opening the entrance of the canal in the central part, the fracture is manipulated and the guide is inserted from the center of the canal into the fractured part. The fracture is kept in place.

Category

Treatment - Surgery

2

Description

Intervention group2: The second group is operated with DHS(versus dynamic hip screw). In this method, after opening the operation site on the DHS bed through a lateral incision, the location of the fracture is determined, and then positioning is done using appropriate traction and maneuvers, and after ensuring its control with radiography, the DHS is placed in the operating room.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Mohamadreza Bozorgmanesh

Street address

Imam khomeyni Ave, Valiasre Blvd, Valiasre Hospital, Arak Town

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Email

mhmmdrz_bzrgmnsh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Davood Hekmatpou

Street address

Sardasht Ave, Chamran Blvd, Arak TOWN

City

Arak

Province

Markazi

Postal code

۳۸۱۹۶۹۳۳۴۰

Phone

+98 86 3313 6055

Email

research@arakmu.ac.ir

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

Mohamad reza Bozorgmanesh

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Valiasr Hospital

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3417 3605

Email

mhmmdrz_bzrgmnsh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohamadreza Bozorgmanesh
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
Street address
Valiasr Hospital
City
Arak
Province
Markazi
Postal code
3819693345
Phone
+98 86 3417 3605
Email
mhmmmdrz_bzrgmnsh@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Mohamadreza Bozorgmanesh
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Orthopedics

Street address
Valiasr Hospital
City
Arak
Province
Markazi
Postal code
3819693345
Phone
+98 86 3417 3605
Email
mhmmmdrz_bzrgmnsh@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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