Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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Name of organization / entity

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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
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Basij Ave, Chamran Blvd, Arak Town
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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 Harriss 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

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Sponsors / Funding sources

1

Sponsor

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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
Mohamad reza Bozorgmanesh

Position
Associate professor

Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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