Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 2026

Comparison of changes in inflammatory factors in patients with intertrochanteric femoral fracture treated with Dynamic Hip Screw surgery with intramedullary nailing

Protocol summary

Study aim

The aim of study was to evaluate inflammatory factors in patients with intertrochanteric femoral fracture treated with dynamic hip screw surgery with intramedullary nailing.

Design

The design of study is a parallel that will be performed with the structure of a three phase clinical trial. In this study, 180 patients will be assigned to surgical groups by dynamic hip screw and intramedullary nailing methods by block randomization. There is no blinding in this study because patients, surgeons, and study outcome assessors are aware of the type of study groups. Randomization will be done using Random Allocation software the blocks will be identified randomly and the groups with the letters A and B.

Settings and conduct

This study was designed to evaluate inflammatory factors in patients undergoing orthopedic surgery due to intertrochanteric femoral fracture. Patients will be selected by considering the inclusion and non-inclusion criteria from the orthopedic ward of Moheb and Rasoul Akram hospitals in Tehran. Then, by block randomization method, we will assign 180 patients to groups with dynamic hip screw and intramedullary nailing surgery.

Participants/Inclusion and exclusion criteria

The criteria considered for the study were confirmed intertrochanteric femoral fracture and age over 18 years. If there are other fractures, the person will not be included in the study.

Intervention groups

Patients in the intervention group will be operated using dynamic hip screw method and patients in the control group will be operated using intramedullary nailing method.

Main outcome variables

C-Reactive Protein; Interleukin 6; Tumor Necrosis Factor alpha

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180530039910N1**
Registration date: **2021-06-08, 1400/03/18**
Registration timing: **prospective**

Last update: **2021-06-08, 1400/03/18**
Update count: **0**

Registration date

2021-06-08, 1400/03/18

Registrant information

Name

Ali Yeganeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6653 9260

Email address

yeganeh.a@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2022-05-19, 1401/02/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of changes in inflammatory factors in patients with intertrochanteric femoral fracture treated with Dynamic Hip Screw surgery with intramedullary nailing

Public title
Comparison of inflammatory factors in Dynamic Hip Screw surgery with intramedullary nailing

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Confirmed intertrochanteric fracture of the femur Over 18 years old
Exclusion criteria:
Having other fractures

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **180**

Randomization (investigator's opinion)
Randomized

Randomization description
After selecting the participants in the study using inclusion and non-inclusion criteria, to prevent the occurrence of bias in the selection of participants to intervention and control groups, we will use the randomization method to minimize the opinion of researchers in selecting participant to study groups. The block randomization method was used in this study. The size of the blocks is considered to be four and will be selected randomly so that it is not predictable to the participants based on the blocks. First, we will receive using Random Allocation software and by determining the sample size, the number of groups, the type of randomization and is random the order of the blocks in the software output and will be shown in the software output of groups with letters A and B. Then, after selecting each patient based on the inclusion and non-inclusion criteria, the project manager will be informed and he will tell the type of intervention of that patient based on the order of inclusion of patients and compliance with the number mentioned in the randomization output.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran university of Medical Sciences
Street address
Iran University of Medical Sciences, Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535

Approval date
2021-02-08, 1399/11/20

Ethics committee reference number
IR.IUMS.REC.1399.1187

Health conditions studied

1

Description of health condition studied
Femoral fracture

ICD-10 code
S72.1

ICD-10 code description
Pertrochanteric fracture

Primary outcomes

1

Description
Serum Level of C-Reactive Protein

Timepoint
One hour before and 24 hours after surgery

Method of measurement
level of serum CRP with Elisa assay

2

Description
Serum Level of Interleukin 6

Timepoint
One hour before and 24 hours after surgery

Method of measurement
level of serum interleukin 6 with Elisa assay

3

Description
Serum level of Tumor Necrosis Factor alpha

Timepoint
One hour before and 24 hours after surgery

Method of measurement
level of serum TNF-α with Elisa assay

Secondary outcomes

1

Description
Nonunion fractures
Timepoint
One month after surgery
Method of measurement
Radiological imaging

Intervention groups

1

Description
Intervention group: Surgery by Dynamic Hip Screw method
Category
Treatment - Surgery

2

Description
Control group: Surgery by Intramedullary nailing method
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul Akram hospital
Full name of responsible person
Ali Yeganeh
Street address
Rasoul Akram hospital, Niyayesh St, Sattarkhan St
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6653 9260
Email
yeganeh.a@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Abbas Motavalian
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway
City
Tehran
Province
Tehran
Postal code
1449614535
Phone
+98 21 8670 2503
Email
research@iums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Sahand Cheraghi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
Rasoul Akram hospital, Niyayesh St, Sattarkhan St
City
Tehran
Province
Tehran
Postal code
1445613131
Phone
+98 21 6653 9260
Email
sahandchera5@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Ali Yeganeh

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

Street address
Rasoul Akram hospital, Niyayesh St, Sattarkhan St

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6653 9260

Email
yeganeh.a@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Sahand Cheraghi

Position
Resident

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

Street address
Rasoul Akram hospital, Niyayesh St, Sattarkhan St

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 6653 9260

Email
sahandchera5@gmail.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
No - There is not 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