

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

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Tehran

Province

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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

Petrochanteric 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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran 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

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

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Person responsible for scientific

inquiries

Contact

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Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

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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)

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