Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the result of intertrochanteric fractures treated with Dynamic Hip Screw (DHS) with or without use of static screw

Protocol summary

Study aim

To evaluate and compare the results of Intertrochanteric fracture treatment by Dynamic Hip Screw (DHS) with or without use of static screws

Design

In this research, we select 40 eligible patients with intertrochantric fracture who refer to Emdadi Shahid Kamyab Hospital purposefully and a code allocate to each one of them. Then, patients are randomly divided into two control and intervention groups.

Settings and conduct

In each group 20 patients choose with intertrochantric fracture who refer to Emdadi Shahid Kamyab Hospital. This reaserch is a single blind radomised clinical trial. After choosing a patient, we tell the patient about the treatment and the study and if desire, he or she enters the study. First, we give the patient a complete explanation for the study and both methods of treatment, If desire, they randomly enter to one of two groups of the study. The surgeon is aware of the study and the type of treatment. The physician who are responsible for completing the questionnaire and examinations are unaware of the details of the study and the rest of the examinations. The statistical authority of the study only contributes to statistical analysis. Only the main investigators know all the details. This is a single blinded research.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Patients with intertrochanteric fracture. Exclusion criteria: Patients with other fractures; Patients with open fracture; Patients with active infection at another point in the body; Patients with pathologic bone diseases; Use of immunosuppressive drug; pregnancy and lactation.

Intervention groups

Intervention group: Patients with intertrochanteric fracture are treating with DHS with Static screw. Control group: Patients with intertrochanteric fracture are treating with DHS without Static screw.

Main outcome variables

The rate of Nonunion, Complications, Mortality and Functional results between the two intervention and control groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170621034689N2**
Registration date: **2018-03-10, 1396/12/19**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-10, 1396/12/19**
Update count: **0**

Registration date

2018-03-10, 1396/12/19

Registrant information

Name

Seyyed Mohammad Ata Sharifi Dalooei

Name of organization / entity

Medical faculty , Orthopaedics departement

Country

Iran (Islamic Republic of)

Phone

+98 935 975 3132

Email address

sharifima921@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the result of intertrochanteric fractures treated with Dynamic Hip Screw (DHS) with or without use of static screw

Public title
Results of intertrochanteric fractures treated with Dynamic Hip Screw (DHS) with or without use of static screw
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with intertrochanteric fracture
Exclusion criteria:
Patients with other fractures. Patients with open fracture. Patients with active infection at another point in the body. Patients with pathologic bone diseases Use of immunosuppressive drug Pregnancy and lactation
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple individual randomization with random number table
Blinding (investigator's opinion)
Single blinded
Blinding description
The surgeon is aware of the study and the type of treatment. The physician who are responsible for completing the questionnaire and examinations are unaware of the details of the study and the rest of the examinations. The statistical authority of the study only contributes to statistical analysis. He is unaware of the scientific issues and goals of the study. Only the main investigators know all the details. This is a single blinded research.
Placebo
Not used
Assignment
Parallel
Other design features
Table of Random numbers

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sience
Street address
Gharshi Building, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Approval date
2015-09-06, 1394/06/15
Ethics committee reference number
1395.4.IR.MUMS.sm.REC

Health conditions studied

1

Description of health condition studied
Intertrochantric fracture
ICD-10 code
S72.143A
ICD-10 code description
Displaced intertrochanteric fracture of unspecified femur, initial encounter for closed fracture

Primary outcomes

1

Description
Union of the fracture.
Timepoint
At intervals 1, 3, 6 and 12 months after surgery.
Method of measurement
Based on clinical signs and symptoms and radiography of the hip.

2

Description
Failure of treatment.
Timepoint
During the course of the treatment, up to one year after the operation.
Method of measurement
Based on symptoms and clinical signs and radiography of the hip; Harris Hip Score; Visual Analogue Scale; Score After Lequesne.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Treatment of Intertrochantric fracture with Dynamic Hip Screw (DHS) device with a placement of an additional Static screw superior to the Dynamic screw.
Category
Treatment - Surgery

2

Description
Control group: Treatment of Intertrochantric fracture with Dynamic Hip Screw (DHS) device.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Emdadi Shahid Kamyab hospital
Full name of responsible person
Seyyed Mohammad Ata Sharifi Dalooei
Street address
Emdadi Shahid Kamyab hospital, Nakhrisi Intersection, Fadaeyan Eslam Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9177899191
Phone
+98 21 3859 6606
Email
sharifima921@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Seyyed Mohmmad Ata Sharifi Dalooei
Street address
Emdadi Shahid Kamyab hospital, Nakhrisi Intersection, Fadaeyan Eslam Street
City
Mashhad
Province
Razavi Khorasan
Postal code
91778-99191
Phone
+98 51 3859 6606
Email
sharifima921@mums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Seyyed Mohammad Ata Sharifi Dalooei
Position
Orthopaedics Resident
Latest degree
Medical doctor
Other areas of specialty/work
Orthopedics
Street address
Emdadi Shahid Kamyab hospital, Nakhrisi Intersection, Fadaeyan Eslam Street
City
Mashhad
Province
Razavi Khorasan
Postal code
91778-99191
Phone
+98 51 3859 6606
Fax
Email
sharifima921@mums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person

Farshid Bagheri

Position

Associate professor of Orthopaedic surgery

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Emdadi Shahid Kamyab hospital, Nakhrisi Intersection, Fadaeyan Eslam Street

City

Mashhad

Province

Razavi Khorasan

Postal code

91778-99191

Phone

+98 51 3859 6606

Fax

Email

bagherif@mums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Seyyed Mohammad Ata Sharifi Dalooei

Position

Orthopaedics Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

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City

Mashhad

Province

Razavi Khorasan

Postal code

91778-99191

Phone

+98 51 3859 6606

Fax

Email

sharifima921@mums.ac.ir

Web page address

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