

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 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 intertrochanteric 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 intertrochanteric 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 Science

**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

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#### 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

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#### Email

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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

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

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#### 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**

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**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

## 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**