Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Dynamic hip screw and Dynamic external fixator in intertrochantric fractures.

Protocol summary

Study aim
Determination the postoperative results in two methods of Dynamic hip screw and Dynamic external fixator in intertrochantric fractures.

Design
Clinical trial; Have control group; each group - 15 patients; Randomized.

Settings and conduct
Patients with intertrochanteric fracture and having conditions in the plan are randomly assigned to one of two groups.In Dynami hip screw(DHS), from side plate with 2 to 4 hole and in Dynamic external fixator two Shanz in the neck of the femur and three in the distal femoral shaft are embedded. Fractures in terms of fracture type and level of osteoporosis, and the rate of complications are compared in two types of fixation.Follow-up will be at least six months.

Participants/Inclusion and exclusion criteria
male or female patients with intertrochantric fractures. Inclusion: Age over 65، fracture of type A1 or A2، one density less than 2.5 in T Score، Ability to walk without help before fracture, Patients at risk of anesthesia III and IV. non inclusion: Previous hip fracturet, Secondary fracture to the tumor, Soft tissue or bone infection in the area, Chemotherapy, Fracture simultaneously in another area.

Intervention groups
Intervention group 1: 15 patients with intertrochantric fracture and using a new external fixator device
Intervention group 2: 15 Patients with intertrochantric fracture and using internal fixator

Main outcome variables
The amount of hematocrit of the blood, Haspitalization, Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181015041344N1**
Registration date: **2019-05-24, 1398/03/03**
Registration timing: **retrospective**

Last update: **2019-05-24, 1398/03/03**
Update count: **0**

Registration date
2019-05-24, 1398/03/03

Registrant information

Name
Meisam Moradi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 51 3802 6122

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moradim941@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-03-21, 1396/01/01

Expected recruitment end date
2019-03-20, 1397/12/29

Actual recruitment start date
2017-03-21, 1396/01/01

Actual recruitment end date
2019-03-20, 1397/12/29

Trial completion date
2019-03-20, 1397/12/29

Scientific title
Comparison of Dynamic hip screw and Dynamic external fixator in intertrochantric fractures.

Public title

Comparison of Dynamic hip screw and Dynamic external fixator in intertrochantric fractures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Intertrochantric fracture of type A1 or A2 Age over 65 years old Bone density less than 2.5 in T score The patient was able to walk without help before the fracture. The patient should be at high anesthetic risk

Exclusion criteria:

Previous hip fracture Secondary fracture to the tumor Soft tissue or bone infection in the area Chemotherapy Simultaneous fracture In the other area

Age

From **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method was performed using a random number table.

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

Ethical Committe of Mashhad University of Medical Sciences

Street address

Ghoreishi Department, Daneshgah St

City

Mashhad

Province

Razavi Khorasan

Postal code

1394491388

Approval date

2017-02-25, 1395/12/07

Ethics committee reference number

IR.MUMS.REC.1395.580

Health conditions studied

1

Description of health condition studied

Comparison of the results of two surgical methods in Treatment Intertrochanteric fracture.

ICD-10 code

S72.3

ICD-10 code description

Fracture of shaft of femur

Primary outcomes

1

Description

pain

Timepoint

before intervention and 6 days after intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

The amount of hematocrit of the blood

Timepoint

before and after intervention

Method of measurement

the blood test

2

Description

Haspitalization

Timepoint

after intervention

Method of measurement

the day number of hospitalization

Intervention groups

1

Description

Intervention group: The use of Dynamic external fixator in patients with intertrochantric fractures

Category

Treatment - Devices

2

Description

Control group: The use of Dynamic hip Screw in patients with intertrochantric fractures

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Reza Hospital

Full name of responsible person
Farshid Bagheri

Street address
Research Center, Imam Reza Hospital, Imam Reza square, Mashhad, Khorasan Razavi, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi

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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
Ali Moradi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Orthopedics

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Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

These data are very specialized and not applicable to the public, and their publication is not obligatory from the authors' point of view.

When the data will become available and for how long

After completing the clinical trial

To whom data/document is available

Orthopeadics

Under which criteria data/document could be used

In order to increase the knowledge and use of new instrument in surgical procedures, after completing the clinical trial and publication of the article can be used.

From where data/document is obtainable

Apply to the email of Dr. Meisam Moradi.

What processes are involved for a request to access data/document

The request has been sent to Dr. Maysam Moradi's email and after being reviewed by him, if necessary, the email will be sent to the person.

Comments