

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Evaluating and comparing the effectiveness of two methods of total hip arthroplasty surgery, conventional method and dual mobility method, in patients with femoral neck fractures, in terms of the amount of time required for rehabilitation and cost.

Protocol summary

Study aim

Comparing the effectiveness of two methods of total hip arthroplasty surgery, the conventional method and dual mobility method, in patients with femoral neck fractures, in terms of the amount of time required for rehabilitation and cost.

Design

This is a clinical trial without a control group, with two parallel groups, open-label, non-randomized, on 80 patients.

Settings and conduct

This study is conducted in Ayatollah Kashani hospital in Isfahan city. Patients with femoral neck fractures were included in the study based on the inclusion criteria and obtaining informed consent and will be treated non-randomly (based on clinical criteria and the specialist's decision) with one of two types of standard or dual mobility methods. Finally, the process of response to treatment 3 months, 6 months, and 12 months after the operation will be compared by examining the recovery time.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 40 to 75 years, femoral neck fracture, and confirming informed consent. Exclusion criteria: underlying diseases that increase the risk of surgery, lack of regular follow-up for visits.

Intervention groups

Intervention group 1: Patients who are candidates for surgery due to femoral neck fracture and undergo THA with the standard method. Intervention group 2: Patients who are candidates for surgery due to femoral neck fracture and undergo THA with the dual mobility method.

Main outcome variables

Recovery time

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210614051574N17**

Registration date: **2023-02-13, 1401/11/24**

Registration timing: **prospective**

Last update: **2023-02-13, 1401/11/24**

Update count: **0**

Registration date

2023-02-13, 1401/11/24

Registrant information

Name

Ghasem Mohammadsharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3729 4005

Email address

mohammadsharifi.ghasem@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-06, 1401/12/15

Expected recruitment end date

2023-05-10, 1402/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating and comparing the effectiveness of two methods of total hip arthroplasty surgery, conventional method and dual mobility method, in patients with femoral neck fractures, in terms of the amount of time required for rehabilitation and cost.

Public title

Evaluation of total hip arthroplasty surgery in femoral neck fractures

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 40 to 75 years Femoral neck fracture Confirming informed consent

Exclusion criteria:

Underlying diseases that increase the risk of surgery
Lack of regular follow-up for visits

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

N/A

Randomization description

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 Esfahan University of Medical Sciences

Street address

Esfahan University of Medical Sciences, Hezar Jarib Ave., Esfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2021-09-28, 1400/07/06

Ethics committee reference number

IR.MUI.MED.REC.1400.516

Health conditions studied

1

Description of health condition studied

Femoral neck fracture

ICD-10 code

S72.0

ICD-10 code description

Fracture of head and neck of femur

Primary outcomes

1

Description

Recovery time

Timepoint

3, 6, and 12 months after surgery.

Method of measurement

Radiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Patients who are candidates for surgery due to femoral neck fracture and undergo THA with the standard method.

Category

Treatment - Surgery

2

Description

Intervention group 2: Patients who are candidates for surgery due to femoral neck fracture and undergo THA with the dual mobility method.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Kashani Hospital

Full name of responsible person

Mostafa Khashei

Street address
Kashani St., Isfahan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
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Isfahan University of Medical Sciences, Hezar Jarib Ave., Daneshgah Blvd, Isfahan
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haghjoo.sh@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mostafa Khashei
Position

Specialist
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Person responsible for updating data

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Fax**Email**

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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

Yes - There is a plan to make this available

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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after people have requested.

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

Send a message to the mentioned e-mail address

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

E-mail the responsible person and if you accept the conditions, the information will be sent.

Comments