

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Comparison of bipolar hemiarthroplasty with reduction and fixation with Dynamic hip screw(DHS) in basicervical femoral neck fractures' patients

#### Protocol summary

##### Study aim

Comparison of outcomes and prognosis of treatment in femoral neck fracture patients with bipolar hemiarthroplasty and plate fixation (Dynamic Hip Screw ) (DHS )

##### Design

A randomized controlled clinical trial with randomized groups with random number table (30 random numbers in each groups) to evaluate and compare surgical outcome and results.

##### Settings and conduct

Patients 60 years and older referred to Taleghani Hospital in Kermanshah city with femoral neck fractures up to first 72 hours after their fracture enrolled in study. By using random table number assigned to two groups, plate fixation and hemi-arthroplasty and operation performed and then patients were evaluated 3 and 6 months after surgery by the Haris Hip Score and Visual Analogue Score as well as complications (infection, union, and fracture) are compared between the two groups

##### Participants/Inclusion and exclusion criteria

Patients undergoing surgical operation due to basicervical femoral neck fracture up to 72 hours after fracture; age 60 or older; No significant cognitive impairment; No chronic disease such as respiratory disease; Ability to walk before fracture without aids

##### Intervention groups

Utilizing two methods : Intervention group with bipolar hemiarthroplasty method and control group with plate fixation with (Dynamic Hip Screw ) (DHS ) were operated.

##### Main outcome variables

Age; Sex; Comorbidities such as osteoarthritis and rheumatoid arthritis, diabetes; Quality of life and activity level based on Haris Hip Score and Visual Analogue Score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180904040953N1**

Registration date: **2020-02-16, 1398/11/27**

Registration timing: **prospective**

Last update: **2020-02-16, 1398/11/27**

Update count: **0**

##### Registration date

2020-02-16, 1398/11/27

##### Registrant information

##### Name

Adel Hojabrian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3836 7989

##### Email address

adel.hojabrian@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-03-04, 1398/12/14

##### Expected recruitment end date

2020-08-18, 1399/05/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of bipolar hemiarthroplasty with reduction and fixation with Dynamic hip screw(DHS) in basicervical femoral neck fractures' patients

#### Public title

Evaluation of bipolar hemiarthroplasty and plating in femoral neck fracture

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Basicervical femoral neck fracture

##### Exclusion criteria:

Re-operation of femoral neck fracture Other limb fractures

#### Age

From **60 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Randomization by a random number table, the researcher first determines the direction of numbers to read (e.g up, down, left or right) as well as considers for the control group,even numbers and the intervention group, odd numbers .Then, the researcher puts his hand on one of the numbers in the predetermined direction and records the numbers and assigns them to the considered group.

#### 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 Kermanshah University of Medical Sciences

###### Street address

Shahid Beheshti Blvd. Kermanshah Town

###### City

Kermanshah

###### Province

Kermanshah

###### Postal code

6715847141

###### Approval date

2020-01-17, 1398/10/27

###### Ethics committee reference number

IR.KUMS.REC.1398.956

### Health conditions studied

#### 1

##### Description of health condition studied

Basicervical femoral neck fracture

##### ICD-10 code

S72.04

##### ICD-10 code description

Fracture of base of neck of femur

### Primary outcomes

#### 1

##### Description

Assessment of quality of life

##### Timepoint

Three and six months after surgery

##### Method of measurement

Haris Hip Score

#### 2

##### Description

Assessment of pain

##### Timepoint

Three and six months after surgery

##### Method of measurement

Visual Analogue scale

### Secondary outcomes

#### 1

##### Description

Union

##### Timepoint

Three and six months after surgery

##### Method of measurement

Radiography

#### 2

##### Description

Infection

##### Timepoint

Six weeks;three months and 6 months after surgery

##### Method of measurement

Clinical judgment; Positive culture;C-reactive protein

### Intervention groups

## 1

### Description

Intervention group: Patients with basicervical femoral neck fracture undergo surgery by bipolar hemiarthroplasty method and compared with the control group 3 and 6 months after surgery for union, infection, and hip assessment score as well as pain score.

### Category

Treatment - Surgery

## 2

### Description

Control group: Patients with basicervical femoral neck fracture undergo surgery by plate fixation(DHS) method and compared with the intervention group 3 and 6 months after surgery for union, infection, and hip assessment score as well as pain score.

### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Taleqani Hospital

**Full name of responsible person**

Ali Mousapour

**Street address**

Shahid Beheshti Blvd. Kermanshah Town

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**Phone**

+98 83 3835 7752

**Fax****Email**

ali.mousapour@kums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Farid Najafi

**Street address**

Shahid Beheshti Blvd. Kermanshah Town

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**Phone**

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**Email**

farid\_n32@yahoo.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kermanshah 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**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Adel Hojabrian

**Position**

Orthopedic Surgery Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Orthopedics

**Street address**

Shahid Beheshti Blvd.Taleqani Hospital. kermanshah city

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Person responsible for updating data**

**Contact**

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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**

Collected data is shareable after people were deidentified.

**When the data will become available and for how long**

Starting 6 months after publication.

**To whom data/document is available**

The data is available only for people who work in academic institutions.

**Under which criteria data/document could be used**

Any analysis isn't allowed on the document.

**From where data/document is obtainable**

The preferred way for communication is via email address: Adel.Hojabrian@kums.ac.ir. The postal address is Kermanshah Town; Shahid Beheshti Blvd; Taleqani hospital. The telephone number is +98 83 38357752 and the contact person is Adel.Hojabrian.

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

The requests will be assessed and the data would be available in one month.

**Comments**