

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### Evaluation of Primary bipolar hemiarthroplasty with distally fixed long stem outcome for unstable intertrochanteric femoral fractures in elderly

#### Protocol summary

##### Study aim

Compare of clinical outcomes of three type of surgery techniques including gamma locking nail, Dynamic Hip Screw (DHS) and Bipolar Hemiarthroplasty in unstable intertrochanteric fracture

##### Design

30 , unrandomise

##### Settings and conduct

The study selected 30 patients referred to Taleghani Hospital in 1394-1395 years. treatment outcomes: patients should be able to walk independently before the fracture to be chosen for study. Patients are examined after an average follow-up of 6 months by the means of functional rate(HHS) and imaging methods.

##### Participants/Inclusion and exclusion criteria

The study selected 30 patients (Both genders with age > 60 yr) with unstable intertrochanteric fracture according to AO/ota classification(31-A3), referred to Taleghani Hospital in 1394-1395 years, . Patients should be able to walk independently before the fracture to be chosen for study.To prevent the distortion of information, the fractures should notbe pathological type and the patient didn't haveany previous fracture at the hip all included cases underwent bipolar hemi arthroplasty with distal fit long stem

##### Intervention groups

Unstable interthrocanthric fracture treated by primary hemiarthroplasty with long stem distal fitted

##### Main outcome variables

Time of surgery; bleeding; harris hip score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180404039188N1**

Registration date: **2018-05-07, 1397/02/17**

Registration timing: **retrospective**

Last update: **2018-05-07, 1397/02/17**

Update count: **0**

##### Registration date

2018-05-07, 1397/02/17

##### Registrant information

###### Name

Reza Zandi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2243 2560

###### Email address

reza.zandi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-04-20, 1395/02/01

##### Expected recruitment end date

2017-04-21, 1396/02/01

##### Actual recruitment start date

2016-04-20, 1395/02/01

##### Actual recruitment end date

2017-04-21, 1396/02/01

##### Trial completion date

empty

##### Scientific title

Evaluation of Primary bipolar hemiarthroplasty with distally fixed long stem outcome for unstable intertrochanteric femoral fractures in elderly

##### Public title

Evaluation of Primary bipolar hemiarthroplasty with distally fixed long stem outcome for unstable intertrochanteric femoral fractures in elderly

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Unstable intertrochanteric fracture; Both gender;  
Patients should be able to walk independently before the fracture to be chosen for study; fractures should not be pathological; no previous fracture at the hip.

### **Exclusion criteria:**

stable fracture disable to walking pathologic fracture  
pervious hip fracture

### **Age**

From **60 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)**

Not randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Single

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Shahid Beheshti University of  
Medical Sciences

##### **Street address**

Tehran,Velenjak,Yaman st,taleghani hospital

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1985711151

#### **Approval date**

2017-07-15, 1396/04/24

#### **Ethics committee reference number**

IR.SBMU.RETECH.REC.1396.109

## **Health conditions studied**

### 1

#### **Description of health condition studied**

intertrochanteric fracture

#### **ICD-10 code**

S72.14

#### **ICD-10 code description**

Intertrochanteric fracture of femur

## **Primary outcomes**

### 1

#### **Description**

improvement of treatment quality

#### **Timepoint**

After 2 months and 6 months and 1 year of treatment

#### **Method of measurement**

questionnaire and. hip radiography

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: fixation with distal fit prothesis

#### **Category**

Treatment - Surgery

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Taleghani hospital

##### **Full name of responsible person**

Reza Zandi

##### **Street address**

Velenjak of Tehran, Taleghani hospital of Erabi st

##### **City**

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## **Sponsors / Funding sources**

### 1

#### **Sponsor**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Reza Zandi

**Street address**

building 2, Shahid Beheshti University,

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**Province**

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1983969411

**Phone**

+98 21 2387 2206

**Email**

reza.zandi@sbmu.ac.ir

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

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Reza Zandi

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Orthopedics

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Reza zandi

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Orthopedics

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**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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**Position**

Associate Professor

**Latest degree**

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**Other areas of specialty/work**

Orthopedics

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**Email**

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**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**

Yes - There is 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

**Title and more details about the data/document**

no information

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

don't choice yet

**To whom data/document is available**

don't choice yet

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

don't choice yet

**From where data/document is obtainable**

don't choice yet

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

don't choice yet

**Comments**