

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

Tehran

Province

Tehran

Postal code

1985711151

Phone

+98 21 2243 2560

Fax

+98 21 2243 2570

Email

reza.zandi@sbm.ac.ir

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,

City

Tehran

Province

Tehran

Postal code

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

Street address

Shahid Beheshti University, Student blvd, Velenjak,
Tehran

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2243 9937

Email

Reza.zandi@sbmu.ac.ir

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

Street address

Shahid Beheshti University, Student blvd, Velenjak,
Tehran

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2243 9937

Email

Reza.zandi@sbmu.ac.ir

Person responsible for updating data**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

Street address

Shahid Beheshti University, Student blvd, Velenjak,
Tehran

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2243 9937

Email

Reza.zandi@sbmu.ac.ir

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