

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jul 2026

### The short-term out comes of acetabular labrum excision in pain and functional scores of patients undergoing bipolar-hemiarthroplasty

#### Protocol summary

##### Study aim

Out comes of acetabular labrum excision in pain and functional scores of patients undergoing bipolar-hemiarthroplasty

##### Design

Two parallel group non-randomized trial with blinded participants, postoperative care and outcome assessment, evaluating postoperative outcomes in bipolar-hemiarthroplasty

##### Settings and conduct

Conducted in an orthopedic hospital between 2020 and 2021, we will perform a new technique of bipolar-hemiarthroplasty (with labrum sxicsion) since the predicted time for IRCT approve. Control group consists of patients who had bipolar-hemiarthroplasty in conventional technique before the start of study. All patients will be informed about the operation excepts the details of technique (labrum excision).

##### Participants/Inclusion and exclusion criteria

Patients with femoral neck fracture, undergoing bipolar-hemiarthroplasty

##### Intervention groups

Intervention consists of acetabular labrum excision in patients undergoing bipolar-hemiarthroplasty, while in control group hemiarthroplasty will be done conventionally.

##### Main outcome variables

1-VAS score: quantitative variable for pain assessment raging form 0-100 2-Harris Hip Score (HSS) questionnaire: has a maximum of 100 points (best possible outcome) covering pain (1 item, 0-44 points), function (7 items, 0-47 points), absence of deformity (1 item, 4 points), and range of motion (2 items, 5 points).

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200521047525N1**

Registration date: **2020-05-26, 1399/03/06**

Registration timing: **prospective**

Last update: **2020-05-26, 1399/03/06**

Update count: **0**

##### Registration date

2020-05-26, 1399/03/06

##### Registrant information

###### Name

Mohammad Movahedinia

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6694 8215

###### Email address

m.movahedinia@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-08-22, 1399/06/01

##### Expected recruitment end date

2022-02-20, 1400/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The short-term out comes of acetabular labrum excision in pain and functional scores of patients undergoing bipolar-hemiarthroplasty

##### Public title

Labrum excision in bipolar-hemiarthroplasty

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with femoral neck fracture, undergoing bipolar-hemiarthroplasty

### Exclusion criteria:

severe medical commodities in non-displaced fractures  
life expectancy < 6 weeks non-displaced fractures in  
painless patients

## Age

No age limit

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **50**

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## Blinding (investigator's opinion)

Single blinded

## Blinding description

All participants included in the study will be informed about the advantageous and complications of the operation. Written informed consent will be obtained from all patients before initiation of the study. But, patients will be blinded about details of surgery techniques (excision or preservation of labrum). This blindness will also be applied for health care providers (including nurses but not the corresponding doctor-surgeon-), data collector (another doctor-not surgeon-), outcome assessor, and draft writer. the corresponding doctor (surgeon) and operating room staffs will be alert about the technique inevitably.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Shahid Beheshti University of Medical Sciences Ethics Committee

## Street address

Shahid Beheshti University of Medical Sciences, Next to Ayatollah Taleghani Hospital, Evin, Tehran, Iran

## City

Tehran

## Province

Tehran

## Postal code

1983963113

## Approval date

2020-03-10, 1398/12/20

## Ethics committee reference number

IR.SBMU.MSP.REC.1398.1016

## Health conditions studied

### 1

#### Description of health condition studied

Fracture of neck of femur in osteoporosis

#### ICD-10 code

S72.0

#### ICD-10 code description

Fracture of neck of femur

### 2

#### Description of health condition studied

osteoporosis

#### ICD-10 code

M80.9

#### ICD-10 code description

Unspecified osteoporosis with pathological fracture

## Primary outcomes

### 1

#### Description

VAS score: The visual analog scale (VAS) is a validated, subjective measure for acute and chronic pain. Scores are recorded by making a handwritten mark on a 10-cm line that represents a continuum between "no pain" and "worst pain."

#### Timepoint

Primary outcome will be measured in 3, 6 and 12 months following the surgery.

#### Method of measurement

The visual analog scale (VAS)

### 2

#### Description

Function assessment by HSS questionnaire: has a maximum of 100 points (best possible outcome) covering pain (1 item, 0-44 points), function (7 items, 0-47 points), absence of deformity (1 item, 4 points), and range of motion (2 items, 5 points).

#### Timepoint

Primary outcome will be measured in 3, 6 and 12 months following the surgery.

#### Method of measurement

HSS questionnaire

## Secondary outcomes

empty

## Intervention groups

1

### Description

Intervention group: Patient of this group will undergo bipolar-hemiarthroplasty with a new technique of acetabular labrum excision.

### Category

Treatment - Surgery

2

### Description

Control group: Patient of this group will undergo bipolar-hemiarthroplasty with conventional technique (preserving the acetabular labrum).

### Category

Treatment - Surgery

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Akhtar hospital

#### Full name of responsible person

Mohammad Movahedinia

#### Street address

Unit1, Floor1, No16, Alley Yousef, St Mirkhani, Sq Tohid

#### City

Tehran

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#### Postal code

1419763594

#### Phone

+98 21 6694 8215

#### Email

mmvn93@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Shahid Beheshti University of Medical Sciences

#### Full name of responsible person

Afshin Zarghi

#### Street address

5th Floor, Bldg No.2, SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

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#### Postal code

1983963113

#### Phone

+98 21 2243 9780

#### Fax

+98 21 2243 9981

#### Email

Mpajouhesh@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

Mohammad Movahedinia

#### Position

Orthopaedic resident

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Orthopedics

#### Street address

Sharifimanesh st.

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m.movahedinia@sbmu.ac.ir

## Person responsible for scientific inquiries

### Contact

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Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Mohammad Movahedinia

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**Person responsible for updating data**

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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**

There is a plan to make clinical study reports and data of this study available to other researchers (typically after the end of the study). These data consist of all variables (except patient's identification) for half of each group participants (control/intervention) provided in SPSS format.

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

The start date of data availability will be in March 2022.

**To whom data/document is available**

Documents will be shared and available for researchers working in any academic institutions.

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

Any requests to access all documents (for example for a systematic review) should be sent to responsible researcher.

**From where data/document is obtainable**

To contact the corresponding researcher: Email: mmvn93@gmail.com WhatsApp: 00989216361088  
Linkedin: mohammad movahedinia

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

After contacting the corresponding researcher, documents will be sent in one month.

**Comments**