

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

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Email

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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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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

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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