

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The comparison of post-operation outcomes of acromioclavicular joint dislocation treatment using hook plate fixation and, arthroscopic and minimal invasive Endobottom system

Protocol summary

Study aim

Determine and comparison of data for hook plate, open, and arthroscopic endobottom systems in ACJ dislocation

Design

A parallel-group, unblinded, randomized clinical trial on 180 patients. Randomization using the block randomization method in SPSS software

Settings and conduct

After obtaining the necessary permits, patients who have suffered an acute dislocation of ACJ and referred to Imam Hussein Hospital are included in the study if they meet the inclusion criteria and also give informed consent.

Participants/Inclusion and exclusion criteria

Including: Acute acromioclavicular joint (ACJ) dislocation (up to 2 weeks after trauma) High-grade dislocation (Rockwood III - V) The capability of follow-up until one year after surgery Not including: Chronic ACJ dislocation (more than three weeks after trauma) Recurrent dislocation ACJ injury type III in patients older than 65 years Data collection is not possible for at least one year after surgery

Intervention groups

- The treated group with hook plate endobottom method
- The treated group with the open endobottom method
- The treated group with hook plate endobottom method

Main outcome variables

Finding a method with fewer complications with faster and more complete rehabilitation in patients with acute ACJ dislocation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221110056460N1**

Registration date: **2022-12-10, 1401/09/19**

Registration timing: **prospective**

Last update: **2022-12-10, 1401/09/19**

Update count: **0**

Registration date

2022-12-10, 1401/09/19

Registrant information

Name

hassan Barati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7756 9991

Email address

dr.hasan.barati@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-19, 1401/11/30

Expected recruitment end date

2023-08-21, 1402/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of post-operation outcomes of acromioclavicular joint dislocation treatment using hook plate fixation and, arthroscopic and minimal invasive Endobottom system

Public title

comparison of Hook plate and Endobottom Results

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Acute acromioclavicular joint (ACJ) dislocation (up to 2 weeks after trauma) High grade dislocation (Rockwood III - V) Capability of follow-up until 1 year after surgery

Exclusion criteria:

Chronic ACJ dislocation (more than 3 weeks after trauma) Recurrent dislocation ACJ injury type III in patients older than 65 years Data collection is not possible for at least 1 year after surgery

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **180**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 Shahid Beheshti University of Medical Sciences

Street address

South Shahid Madani St., Imam Hussein Hospital

City

Tehran

Province

Tehran

Postal code

1617763141

Approval date

2022-04-24, 1401/02/04

Ethics committee reference number

IR.SBMU.RETECH.REC.1401.040

Health conditions studied

1

Description of health condition studied

Subluxation and dislocation of acromioclavicular joint

ICD-10 code

S43.1

ICD-10 code description

Subluxation and dislocation of acromioclavicular joint

Primary outcomes

1

Description

Constant Score

Timepoint

Before surgery, 6 months after surgery, 12 months after surgery

Method of measurement

survey

2

Description

The University of California Los Angeles Shoulder score

Timepoint

Before surgery, 6 months after surgery, 12 months after surgery

Method of measurement

survey

3

Description

Visual Analogue Scale

Timepoint

Before surgery, 6 months after surgery, 12 months after surgery

Method of measurement

survey

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Treated with hook plate

Category

Treatment - Surgery

2

Description

Intervention group: Treated with open endobottom method

Category

Treatment - Surgery

3

Description

Intervention group: Treated with arthroscopic endobottom method

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hussein Hospital

Full name of responsible person

Hasan Barati

Street address

South Shahid Madani

City

Tehran

Province

Tehran

Postal code

1617763141

Phone

+98 21 7343 0000

Email

dr.hasan.barati@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Sahid Arabi

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9781

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

Seyyed Alireza Mohseni Sangtabi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

South Shahid Madani

City

Tehran

Province

Tehran

Postal code

1617746510

Phone

0989109448358

Email

aalirezamohseni90@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyyed Alireza Mohseni Sangtabi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

South Shahid Madani

City

Tehran

Province

Tehran

Postal code

1617746510

Phone

0989109448358

Email

aalirezamohseni90@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyyed Alireza Mohseni Sangtabi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

South Shahid Madani

City

Tehran

Province

Tehran

Postal code

1617746510

Phone

0989109448358

Email

aalirezamohseni90@gmail.com

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

No - There is not a plan to make this available

Title and more details about the data/document

The data of the patients will be added as a supplement upon the request of the publication publishing the study results. The study protocol will be presented as a method in this study's published article. The statistical analysis roadmap will be presented in the form of the implementation method in the published article of the present study. The informed consent form will be attached at the request of the publication publishing the study results. The clinical study report will be published in a research paper in one of the prestigious international scientific journals. When the research paper is published, the codes used in data analysis will be attached in the form of R or SPSS files.

When the data will become available and for how long

After the publication of the research article

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

It is possible to copy, publish, display and perform works and derivative works only for non-commercial purposes.

From where data/document is obtainable

Seyyed Alireza Mohseni Sangtabi, Orthopaedics resident, 0989109448358, aalirezamohseni90@gmail.com

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

Call or mail

Comments