Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The comparison of post-operation outcomes of acromioclavicular joint dislocation treatment using hook plate fixation and, arthroscopic and minimal invasive Endobuttom 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
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Name of organization / entity
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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 Endobuttom system

Public title

comparison of Hook plate and Endobuttom 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
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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
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1985717443
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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
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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
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
Seyed Alireza Mohseni Sangtabi, Orthopaedics resident, 0989109448358, aalirezamohseni90@gmail.com

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

Comments