

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Clinical evaluation on acromioclavicular joint dislocations; A) Ethibond suture peri-clavicular loop vs B) Ethibond suture through two holes in clavicle

Protocol summary

Summary

(1) Objectives: to compare the therapeutic effects of two different techniques in the treatment of ACJ dislocation (2) Design: Randomized controlled trial. (3) Setting and conduct: Sample size of 76 patients will randomly assign into A) Ethibond suture peri-clavicular loop vs B) Ethibond suture through two holes in clavicle and will be treated in academic orthopedic hospital. (4) Participants: Inclusion criteria: patients with: age>18 years, clinically and radiographically diagnosed as acute acromioclavicular joint dislocation (in the first 3 weeks) with grade III-VI . Exclusion criteria: age>65 years, chronic dislocation, history of previous shoulder trauma, concomitant lesion in the suffered arm. (5) Interventions: A) Ethibond suture peri-clavicular loop vs B) Ethibond suture through two holes (6) Main outcome measures: Primary outcome is horizontal displacement status of radiography of the acromioclavicular joint

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201704087274N12**
Registration date: **2017-04-12, 1396/01/23**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-04-12, 1396/01/23

Registrant information

Name

Mohsen Mardani Kivi

Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Guilan University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2017-05-22, 1396/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation on acromioclavicular joint dislocations; A) Ethibond suture peri-clavicular loop vs B) Ethibond suture through two holes in clavicle

Public title

Shoulder joint dislocation surgeries: a comparison between two techniques

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with: age>18 years, clinically and radiographically diagnosed as acute acromioclavicular joint dislocation (in the first 3 weeks) with grade III-VI . Exclusion criteria: age>65 years, chronic dislocation, history of previous shoulder trauma,

concomitant lesion in the suffered arm.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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, Guilan University of Medical Sciences

Street address

Research vice-chancellor of Guilan university of medical sciences building, Shahid Beheshti blv.

City

Rasht

Postal code

Approval date

2017-01-14, 1395/10/25

Ethics committee reference number

IR.GUMS.REC.1395.307

Health conditions studied

1

Description of health condition studied

Dislocation of acromioclavicular joint

ICD-10 code

S43.1

ICD-10 code description

Dislocation of acromioclavicular joint

Primary outcomes

1

Description

Horizontal status of radiography of the acromioclavicular joint

Timepoint

pre-operation visit, three, six and twelve monthes folow ups

Method of measurement

using a ruler with milimeter

Secondary outcomes

1

Description

Functional shouldet status

Timepoint

Pre-operation, third, sixth, and twelve monthes follow ups

Method of measurement

Taft score

2

Description

Functional shouldet status

Timepoint

Pre-operation, third, sixth, and twelve monthes follow ups

Method of measurement

Constant score

3

Description

Functional shouldet status

Timepoint

Pre-operation, third, sixth, and twelve monthes follow ups

Method of measurement

Acromioclavicular joint instability score

Intervention groups

1

Description

Group A (AC joint repair using two holes): In this group the Ethibond-5 suture will be folded and will be pass underneath the coracoid process and it will be pass through two holes which will be created in the clavicle. after acromioclavicular joint reduction the suture will be knotted.

Category

Treatment - Surgery

2

Description

In the second group, instead of passing the suture anchor through holes, it will be looped around the clavicle and coracoid. After reducing the

acromioclavicular joint, the anchore suture will be knotted

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam-Reza Clinic of Poursina Hospital

Full name of responsible person

Mohsen Mardani Kivi MD.

Street address

Imam-Reza clinic, Poursina hospital, Parastar avenue

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Guilan University of Medical Sciences

Full name of responsible person

Abtin Heydarzadeh MD, Research chancellor of Guilan university of medical science

Street address

Research vice-chancellor of Guilan university of medical sciences building, Shahid Beheshti blv.

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Guilan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Guilan University of Medical Science

Full name of responsible person

Mohsen Mardani Kivi MD.

Position

Associated Professor

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty