Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jul 2026

Comparison results of acromioclavicular dislocations treatment by screw, with and without coracoclavicular suture in patients with acute acromioclavicular dislocations

Protocol summary

Summary

- Aim of study: comparing two surgical methods in acute dislocations of acromiococlavicular joint by using absorbable suture and coracoclavicular screw - Designing the study: randomized controlled trial,not blinded,two-centered - Main inclusion criteria: No history of surgery and former trauma in the same shoulder joint and upper limb -Main exclusion criteria: multi traumatic patients and type 3 and 6 dislocations - Population being studied: Patients with acute Acromioclavicular joint dislocations The volume of the sample: 40 patients The intervention being studied: open reduction and fixation with screw and coracoclavicular suture with the one without suture Duration of intervention: 4 years Primary outcome measures:Constant score, Visual Analog Score (VAS), and restoring shoulder function

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014061018030N1**
Registration date: **2014-11-09, 1393/08/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-11-09, 1393/08/18

Registrant information

Name

Meisam Baiman

Name of organization / entity

Medicine Faculty of Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3440 4372

Email address

elmia@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

With the support of Vice Chancellor for research of Tabriz University of Medical Sciences

Expected recruitment start date

2010-03-20, 1388/12/29

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison results of acromioclavicular dislocations treatment by screw, with and without coracoclavicular suture in patients with acute acromioclavicular dislocations

Public title

The comparison between two surgical methods in acute dislocations of acromiococlavicular joints

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Informed consent for participating in the trial ; No history of surgery and former trauma in the same shoulder joint and upper limb ; No history of systemic disorders such as Diabetes and hyperthyroidism or hypothyroidism ; No history of former

pathology in the same joint such as calcified tendinitis ; No simultaneous fractures in the time of damage Exclusion criteria: Multi traumatic patients ; type 3 and 6 dislocations

Age
From **20 years** old to **54 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
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
Research council of Ethics Committe of Tabriz University of Medical Sciences

Street address
Research deputy, third floor, central building number 2, Tabriz University of Medical Sciences,Golgasht street

City
Tabriz

Postal code

Approval date
2009-01-20, 1387/11/01

Ethics committee reference number
93112

Health conditions studied

1

Description of health condition studied
Acute dislocations of acromioclavicular joint

ICD-10 code
s43.1

ICD-10 code description
Dislocations of Acromioclavicular joint

Primary outcomes

1

Description
constant

Timepoint
third,sixth and twelfth weeks after intervention

Method of measurement
standard Constant questionnaire

2

Description
restoring shoulder function

Timepoint
Three and six months after intervention

Method of measurement
Restoring the shoulder range of motion

3

Description
Visual Analog Scale (VAS)

Timepoint
Thirs, sixth, and twelfth weeks after intervention

Method of measurement
Based on patients' statements, subjectively

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In this group in addition to open reduction and fixation with screw, coracoclavicular suture with 3 bands of absorbable sutures(Vicryle)was used.

Category
Treatment - Surgery

2

Description
Control group:20 patients in control group were only fixated by coracoclavicular screw withou any sutures.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Shohada Hospital

Full name of responsible person
Asghar Elmi

Street address
Orthopedics educational group, Shohada Hospital, Golshahr street, El Goli broadway
City
Tabriz

2

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Asghar Elmi
Street address
Imam Reza Hospital, Daneshgah street
City
tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Tabriz University of Medical Sciences
Full name of responsible person
Saeid Aslanabadi
Street address
Orthopedics educational group, Shohada Hospital, Golshahr street, El Goli broadway
City
Tabriz
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 of Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Asghar Elmi
Position
Orthopedician
Other areas of specialty/work
Street address
Orthopedics educational group, Shohada Hospital, Golshahr street, El Goli broadway
City
Tabriz
Postal code
Phone
+98 41338593147
Fax
Email
elmimail@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Asghar Elmi
Position
Orthopedician
Other areas of specialty/work
Street address
Orthopedics educational group, Shohada Hospital, Golshahr street, El Goli broadway
City
Tabriz
Postal code
Phone
+98 41338593147
Fax
Email
elmimail@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Asghar Elmi
Position
Orthopedician
Other areas of specialty/work
Street address
Orthopedics educational group, Shohada Hospital, Golshahr street, El Goli broadway
City
Tabriz
Postal code
Phone
+98 41338593147
Fax
Email
elmimail@yahoo.com
Web page address

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