

# 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 acromioclavicular 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 acromioclavicular 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 without 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

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+98 41338593147

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elmimail@yahoo.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

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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*