

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Randomized controlled trial of intra-articular versus sub-pectoral long head of bicep tenodesis in the treatment patients with biceps pathology accompanied with rotator cuff tears

#### Protocol summary

##### Summary

(1) Objectives: to compare intra-articular versus sub-pectoral long head of bicep tenodesis in the treatment of biceps pathology accompanied with rotator cuff tears. (2) Design: Randomized controlled trial. (3) Setting and conduct: Sample size of 60 patients will randomly assign into intervention (Intra-articular) or control (sub-pectoral) group and will be treated in academic orthopedic hospital. (4) Participants: Inclusion criteria: All rotator cuff tore patients with at least one positive biceps tendon test; Inflammation, partial tear, dislocation, or SLAP lesion; Age between 14 and 65 years; No sign of extensive fatty infiltration in MRI. Exclusion criteria: History of shoulder surgery; Pain or need for surgery of both shoulders; Impossible arthroscopic repair of rotator cuff during surgery and change of arthroscopic surgery into open surgery. (5) Interventions: Intra-articular tenodesis using anchor sutures will be performed in the first group. In the second group, after intra-articular tenotomy, mini open sub pectoral approach will be employed to execute tenodesis using bio absorbable interference screw. (6) Main outcome measures: Primary outcome is VAS score of pain which will be assessed pre-treatment, 6 month and one year after surgery. Secondary outcomes are VAS score of patients satisfaction, Constant score and simple shoulder test.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201309247274N9**

Registration date: **2013-10-23, 1392/08/01**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2013-10-23, 1392/08/01

##### Registrant information

###### Name

Mohsen Mardani Kivi

###### Name of organization / entity

Guilan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 1321 1470

###### Email address

mardani@gums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Guilan University of Medical Sciences

##### Expected recruitment start date

2013-06-17, 1392/03/27

##### Expected recruitment end date

2014-06-20, 1393/03/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Randomized controlled trial of intra-articular versus sub-pectoral long head of bicep tenodesis in the treatment patients with biceps pathology accompanied with rotator cuff tears

##### Public title

Comparison between two tenodesis methods in the

treatment of biceps tendon and shoulder pathology.

#### **Purpose**

Treatment

#### **Inclusion/Exclusion criteria**

Inclusion criteria: All rotator cuff tear patients with at least one positive biceps tendon test (speed test, Yergoson test, active compression test or biceps instability); Inflammation, partial tear, dislocation, or SLAP lesion; Age between 14 and 65 years; No sign of extensive fatty infiltration in MRI. Exclusion criteria: History of shoulder surgery; Pain or need for surgery in both shoulders; Impossible arthroscopic repair of rotator cuff during surgery and change of arthroscopic surgery into open surgery.

#### **Age**

From **14 years** old to **65 years** old

#### **Gender**

Both

#### **Phase**

2-3

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **60**

#### **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**

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**

2013-06-17, 1392/03/27

##### **Ethics committee reference number**

1920101207

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Long head of biceps tendinitis

##### **ICD-10 code**

M75.2

##### **ICD-10 code description**

Bicipital tendinitis

### **Primary outcomes**

#### **1**

##### **Description**

Pain intensity

##### **Timepoint**

before, 6 months and one year after surgery

##### **Method of measurement**

Visual Analogue Scale score (VAS)

### **Secondary outcomes**

#### **1**

##### **Description**

Patient satisfaction

##### **Timepoint**

before, 6 months and one year after surgery

##### **Method of measurement**

Visual Analogue Scale score (VAS)

#### **2**

##### **Description**

Functional status of shoulder

##### **Timepoint**

Before, 6 months and one year after surgery

##### **Method of measurement**

Constant score

#### **3**

##### **Description**

Functional status of shoulder

##### **Timepoint**

Before, 6 months and one year after surgery

##### **Method of measurement**

Simple Shoulder Test

### **Intervention groups**

#### **1**

##### **Description**

First group-intervention (Intra-articular tenodesis): During arthroscopic treatment of rotator cuff tear, Intra-articular tenodesis using anchor sutures will be performed.

##### **Category**

Treatment - Surgery

## 2

### Description

Second group-Control (Sub-pectoral tenodesis): After intra-articular tenotomy, mini open sub pectoral approach will be employed to execute tenodesis using bio absorbable interference screw.

### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Imam-Reza Clinic of Poursina Hospital

**Full name of responsible person**

Dr Mohsen Mardani Kivi

**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**

Dr. Abdolrasoul Sobhani, Research chancellor of Guilan university of medical science

**Street address**

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

**City**

Rasht

**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**

Dr. Mohsen Mardani Kivi

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

Orthopedic Department, Poursina Hospital, Parastar avenue.

**City**

Rasht

**Postal code****Phone**

+98 13 1321 1470

**Fax****Email**

dr\_mohsen\_mardani@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Guilan University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Mardani Kivi

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

Orthopedic Department, Poursina Hospital, Parastar avenue

**City**

Rasht

**Postal code****Phone**

+98 13 1321 1470

**Fax****Email**

dr\_mohsen\_mardani@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Guilan University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Mardani Kivi

**Position**

Orthopedic Surgeon, Assistant Professor

**Other areas of specialty/work****Street address**

Orthopedic Department, Poursina Hospital, Parastar avenue

**City**

Rasht

**Postal code**

**Phone**

+98 13 1321 1470

**Fax**

**Email**

dr\_mohsen\_mardani@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*