

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

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Email address

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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

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City

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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

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Position

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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