

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Comparison between therapeutic responses to ultrasound, low level LASER+ultrasound, sonographically guided extra and intra tendon's sheath corticosteroid injection in the treatment of long head of biceps tendinitis

Protocol summary

Summary

(1) Objectives: Comparison between therapeutic responses to ultrasound, low level LASER+ultrasound, sonographically guided extra and intra tendon's sheath corticosteroid injection in the treatment of long head of biceps tendinitis. (2) Design: Randomized controlled trial. (3) Setting and conduct: Sample size of 144 patients will randomly assign into intervention (low level LASER+ultrasound, sonographically guided extra and intra tendon's sheath corticosteroid injection) or control (ultrasound) group and will be treated in academic orthopedic hospital.(4) Participants: Inclusion criteria: Presence of pain in shoulder or upper extremity for more than 3 months; Point tenderness in bicipital groove; At least one positive biceps tendon test; No partial or complete rotator cuff tear. Exclusion criteria: History of shoulder surgery or injection; Calcification in rotator cuff; Dislocation, subluxation, partial or complete tear of long head of biceps tendon; Frozen shoulder; Diabetes mellitus.(5) Interventions:Ten five-minute secessions of ultrasound in ultrasound group, ultra sound group treatment plus low level laser therapy in every session in LASER+ultrasound group, Injection of 1ml of methylprednisolon acetate 40 mg/ml under ultrasound guide inside and outside of the tendon sheath in other two groups. (6) Main outcome measures: Primary outcome is VAS score of pain which will be assessed pre-treatment, 1 week, 1 month, 3 months and one year after intervention. Secondary outcome is Constant-Morley score.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201502257274N11**

Registration date: **2015-03-09, 1393/12/18**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-03-09, 1393/12/18

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

2014-05-22, 1393/03/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between therapeutic responses to ultrasound, low level LASER+ultrasound, sonographically guided extra and intra tendon's sheath corticosteroid injection in the treatment of long head of biceps tendinitis

Public title

Comparison between four therapeutic methods in the treatment of long head of biceps tendinitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Presence of pain in shoulder or upper extremity for more than 3 months; Point tenderness in bicipital groove; At least one positive biceps tendon test (active compression test, Yergoson test, speed test or biceps instability); No evidence of partial or complete rotator cuff tear. Exclusion criteria: History of shoulder surgery or injection; Any calcification (or calcareous deposit) in rotator cuff; Any sign of dislocation, subluxation, partial or complete tear of long head of biceps tendon; Frozen shoulder; Diabetes mellitus.

Age

From **14 years** old to **139 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **144**

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

2014-10-27, 1393/08/05

Ethics committee reference number

1930349903

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

VAS score of pain which will be assessed pre-treatment, 1 week, 1 month, 3 months and one year after intervention

Method of measurement

Visual Analogue Scale score (VAS)

Secondary outcomes

1

Description

Functional status of shoulder

Timepoint

pre-treatment, 1 week, 1 month, 3 months and one year after intervention

Method of measurement

Constant-Morley score

Intervention groups

1

Description

First group-control (Ultrasound): 10 session (3 session a week) of ultrasound (frequency:1MHz, intensity:1W/cm², Cycle: 2:8, Transducer section area: 5 cm²) for 5 minutes will administer in this group

Category

Rehabilitation

2

Description

Second group-intervention (Ultrasound+Low level LASER): In addition to ultrasound like the first group, the Ga-As-Al LASER (Wave Length:830 nm, Power:30mW, Intensity:1 J/cm², Beam diameter:4mm, Angle:2.5 degree) with a pencil probe will be execute.

Category

Rehabilitation

3**Description**

Third group-intervention (Intra tendon sheath injection): 1 ml of Methylprednisolon acetate (40 mg/ml) with 1ml of Lidocaine 2% will be injected into the long head of biceps tendon sheath using a 1.5 inches 25 gauge needle under the guide of ultrasound. From the day after injection ultrasound will be administered same as the control group.

Category

Treatment - Drugs

4**Description**

Fourth group-intervention (Extra tendon sheath injection): All devices and methods are similar to the third group but the injection will be executed outside the tendon sheath.

Category

Rehabilitation

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.

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

Mohsen Mardani Kivi MD.

Position

Assistant Professor

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

Orthopedic Department, Poursina Hospital, Parastar avenue.

City

Rasht

Postal code**Phone**

+98 13 3331 1470

Fax**Email**

dr_mohsen_mardani@yahoo.com

Web page address<http://www.dr-mardani.com>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Guilan University of Medical Sciences

Full name of responsible person

Mohsen Mardani Kivi MD.

Position

Assistant Professor

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

Orthopedic Department, Poursina Hospital, Parastar avenue

City

Rasht

Postal code**Phone**

+98 13 3331 1470

Fax**Email**

dr_mohsen_mardani@yahoo.com

Web page address<http://www.dr-mardani.com>

Person responsible for updating data

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Mohsen Mardani Kivi MD.

Position

Assistant Professor

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

Orthopedic Department, Poursina Hospital, Parastar
avenue

City

Rasht

Postal code**Phone**

+98 13 3331 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