Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Lenght: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
rthopedic 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