Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effects of high intensity laser therapy on clinical and sonogeraphy findings in patients with rotator cuff tendinitis

Protocol summary

Study aim
The effect of high intensity laser on rotator cuff tendonitis will be investigated.

Design
Clinical trial of 32 participants with control group, with parallel groups, double blind, randomized block.

Settings and conduct
Thirty-two patients with rotator cuff tendonitis will be referred to a physiotherapy clinic and will receive physiotherapy services within 12 sessions depending on the control group or treatment by a physiotherapist.

Participants/Inclusion and exclusion criteria
Inclusion criteria: diagnosis of rotator cuff tendonitis based on clinical examination; movement restriction; pain more than 1 month with visual analog scale 3-7; evidence of subacromial fluid accumulation around the tendon; age range 20-60 years old. Exclusion criteria: history of shoulder surgery; neoplastic disease; systemic inflammatory diseases; full rotator cuff tendon rupture based on ultrasound evidence; history of corticosteroid injection over the past 6 months.

Intervention groups
Thirty-two patients in the study will be divided into two groups of 16 in each treatment and control group. Both treatment and control groups will receive 1 tablet of diclofenac 100 mg daily for the first 10 days after tendon rotator cuff rotation diagnosis. Hot packs in tendonitis area and pulsed ultrasound will be used in internal shoulder rotation. In the treatment group, in addition to the conventional physiotherapy mentioned in the control group, a pulsed 808 nano meter pulse laser with a mean power of 4 watts will be used. Both groups ROM training, including WAND exercises and strengthening the rotator cuff muscles of pain-free range. Ultrasound evaluation of the rotator cuff tendon in both treatment and control groups will be performed.

Main outcome variables
The effect of high power laser on increasing range of motion; reducing pain; decreasing subacromial fluid around the tendon; returning to daily activity.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20191127045528N1**
Registration date: **2020-02-23, 1398/12/04**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-23, 1398/12/04**
Update count: **0**

Registration date
2020-02-23, 1398/12/04

Registrant information

Name
morteza beyrami

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 41 3235 6488

Email address
morteza.beyrami.pt@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-12, 1398/09/21

Expected recruitment end date
2020-12-11, 1399/09/21

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effects of high intensity laser therapy on clinical and sonogeraphy findings in patients with rotator cuff tendinitis

Public title
Effects of high intensity laser therapy on rotator cuff tendinitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis for rotator cuff tendinitis Range of motion restriction Pain range 3-7 in visual analog scale Increase liquid in subacromial space Age between 20-60 years old
Exclusion criteria:
Shoulder surgery Neoplastic disease systemic inflammation disease Complate tearing of rotator cuff Cervical discopathy Corticosteroids injection Shoulder fracture physical therapy in shoulder Axillary lymphoedem Myofasica syndrom Pain killer user Diabetic disease
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
32 patients will be selected by simple non-probability sampling. After completing the informed consent form, the research will be randomly blocked with forth blocked size will be divided into two groups of 16; treatment and control groups.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants will be empowered with placebo without the knowledge of a kind of powerful laser.The respected colleague evaluates in which group, without knowing the people in the group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of tabriz university of medical sciences
Street address
Third Floor Vice Chancellor for Research and Technology, Building No. 2, Tabriz University of Medical Sciences, Golgasht Street
City
Tabriz
Province
East Azarbaijan
Postal code
5147746734
Approval date
2019-11-12, 1398/08/21
Ethics committee reference number
IR.TBZMED.REC.1398.837

Health conditions studied

1

Description of health condition studied
People with rotator cuff tendinitis
ICD-10 code
M75.1
ICD-10 code description
Rotator cuff syndrome

Primary outcomes

1

Description
Effects of high intensity laser therapy in increasing of shoulder range of motion.
Timepoint
Measurement of shoulder range of motion in the first study and after 12 sessions of laser therapy
Method of measurement
Goniometry

2

Description
The effect of high power laser on pain relief in people with shoulder tendonitis will be determined.
Timepoint
Measurement of shoulder pain in the first study and after 12 sessions of laser therapy.
Method of measurement
Visual Analogue Scale

3

Description
The effect of high power laser on decreasing sub

acromial fluid around the tendon in people with rotator cuff tendonitis will be determined based on ultrasound images.

Timepoint

Measurement of subacromial fluid around the tendon in the first study and after 12 sessions of laser therapy.

Method of measurement

Musculoskeletal ultrasound

4

Description

The effect of a powerful laser on returning to the daily activities of people with shoulder tendonitis will be determined.

Timepoint

Return to daily activity at baseline and after 12 sessions of laser therapy.

Method of measurement

Shoulder pain and disability questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

16 patients participating in the study who were selected by simple non-probability sampling. Before using the modalities, the pain scale with "VAS scale" and the degree of disability by the "Pain and Shoulder Disability Questionnaire" were administered to patients. The data will be evaluated. Also, the range of motion of the shoulder in the directions of flexion, abduction and external and internal rotation by "goniometry" and the amount of subacromial fluid accumulation around the rotator cuff tendon will be measured by "sonography" treatment groups will receive 1 tablet of diclofenac 100 mg daily for the first 10 days after rotator cuff tendonitis. After the 10 day treatment period, diclofenac will be administered.Intervention group: In addition to the conventional physiotherapy, the 808 nm pulsed laser pulse laser with an average power of 4 watts and a power density of 20 joule / cm2 and frequency of 20 Hz will be used at 10 painful points and ROM exercises including WAND exercises to increase range of motion,flexion, external rotation, abduction, internal rotation and pendular training in the first 6 sessions and rotator cuff muscles strengthening and scapular stabilizers in the final 6 sessions. No pain was given.Marinate will initially be trained in a 3 set of 10 sets at the clinic to evaluate the proper performance under the supervision of a physiotherapist. If pain is reported during each exercise, the exercise will be stopped and re-examined after a few sessions.These exercises will be performed once a day, with 3 sessions of 10 sessions per day as a home exercise. (12 sessions in total). At the end of physiotherapy sessions, pain and range of motion، Shoulder pain and disability questionnaireare measured by a physiotherapist who is unaware of the treatment and The amount of fluid accumulation around the tendon will also be monitored by a physician.

Category

Rehabilitation

2

Description

Control group:16 patients participating in the study who were selected by simple non-probability sampling. Before using the modalities, the pain scale with "VAS scale" and the degree of disability by the "Pain and Shoulder Disability Questionnaire" were administered to patients. The data will be evaluated. Also, the range of motion of the shoulder in the directions of flexion, abduction and external and internal rotation by "goniometry" and the amount of subacromial fluid accumulation around the rotator cuff tendon will be measured by "sonography" control group will receive 1 tablet of diclofenac 100 mg daily for the first 10 days after rotator cuff tendonitis. After the 10 day treatment period, diclofenac will be administeredIn addition to the conventional physiotherapy,placebo high power laser therapy be used for them and ROM exercises including WAND exercises to increase range of motion flexion, external rotation, abduction, internal rotation and pendular training in the first 6 sessions and rotator cuff muscles strengthening and scapular stabilizers in the final 6 sessions. No pain was given.At the end of physiotherapy sessions, pain and range of motion، Shoulder pain and disability questionnaire are measured by a physiotherapist who is unaware of the control and The amount of fluid accumulation around the tendon will also be monitored by a physician.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Sadra physiotherapy clinic

Full name of responsible person

Morteza Beyrami

Street address

No,5, jahan seyr building,saadi jonobi Ave,vali asr

City

Tabriz

Province

East Azarbaijan

Postal code

514777346

Phone

+98 41 3235 6488

Email

morteza.beyrami.pt@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Aboulgasem Joyban
Street address
Central Building of Tabriz University of Medical Sciences, Golgasht St.,Azadi St.
City
Tabriz
Province
East Azarbaijan
Postal code
514777346
Phone
+98 41 3335 7311
Fax
+98 41 3334 4280
Email
info@medfac.tbzmed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Tabriz university of medical science.

Proportion provided by this source
1

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Morteza Beyrami
Position
University student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
Next to Imam Reza Hospital School of Medicine / Golgasht Street /Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
514777346
Phone
+98 41 3337 6923
Fax
Email
info@medfac.tbzmed.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Morteza Beyrami
Position
University student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
Next to Imam Reza Hospital School of Medicine / Golgasht Street /Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
514777346
Phone
+98 41 3337 6923
Fax
Email
info@medfac.tbzmed.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Morteza Beyrami
Position
University student
Latest degree
Bachelor
Other areas of specialty/work
Physiotherapy
Street address
Next to Imam Reza Hospital School of Medicine / Golgasht Street /Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
514777346
Phone
+98 41 3337 6923

Fax

Email

info@medfac.tbzmed.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no more information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

I can share treatment protocol and report completely.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

Researcher

Under which criteria data/document could be used

If they cited to me.

From where data/document is obtainable

email:morteza.beyrami.pt@gmail.com phone no:09354221820 name:Morteza beyrami

What processes are involved for a request to access data/document

After being approved by the University as a researcher the Documentation shared with you.

Comments