

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

A comparative study of the effects of low and high power laser therapy in partial tear of the supraspinatus tendon with use of ultrasonography in 20 to 40 years old subjects with shoulder pain.

Protocol summary

Study aim

A comparative study of the effects of low and high power laser therapy in partial tear of the supraspinatus tendon with use of ultrasonography in 20 to 40 years old subjects with shoulder pain.

Design

Interventional clinical trial with two treatment groups and parallel groups, double-blind, randomized with 8-week follow-up on 40 patients

Settings and conduct

After determining the size of the tear and other sonographic parameters, as well as measuring the intensity of pain, range of motion, and pain and disability index, patients are randomly divided into two treatment groups. Patients will be treated in the physiotherapy clinic of Rehabilitation faculty of Shahid Beheshti University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 20 to 40 years, With partial tear of Grade 1 and 2 Neer classification in supraspinatus tendon, with or without tearing in other rotator cuff tendons, Has partial tear of Grade 1 and 2 that has been confirmed by MRI, Positive at least two specific jobe supraspinatus test, Neer and hawkin kennedy, Partial tear of the supraspinatus muscle tendon with pain in the shoulder area for at least 3 months and up to one year, Patients with a pain score of 5 or higher as determined by the visual analogue scale. Exclusion criteria: Full thickness tear, and implants in the shoulder area, steroid injection, Hook-shaped acromion, Rheumatoid arthritis, Diabetes, Neurological disorders, heat disturbance, people who have undergone radiotherapy in the last 6 months

Intervention groups

Treatment group 1: people were treated with ice, low power laser and exercise. Group 2: In this group, people were treated with ice, high power laser and exercise.

Main outcome variables

Echogenicity of supraspinatus tendon, supraspinatus tendon thickness, pain intensity (based on visual analog scale), range of motion, pain level and disability (SPADI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211012052742N1**

Registration date: **2021-10-19, 1400/07/27**

Registration timing: **prospective**

Last update: **2021-10-19, 1400/07/27**

Update count: **0**

Registration date

2021-10-19, 1400/07/27

Registrant information

Name

Ali Khoshdel

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3224 4488

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-30, 1400/08/08

Expected recruitment end date

2022-04-28, 1401/02/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effects of low and high power laser therapy in partial tear of the supraspinatus tendon with use of ultrasonography in 20 to 40 years old subjects with shoulder pain.

Public title

The effect of laser therapy on the treatment of partial tear of the supraspinatus tendon

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 20 to 40 years With partial tear of Grade 1 and 2 Neer classification in supraspinatus tendon, with or without tearing in other rotator cuff tendons Has partial tear of Grade 1 and 2 that has been confirmed by MRI Positive at least two specific jobe supraspinatus test, Neer and hawkin kennedy Partial tear of the supraspinatus muscle tendon with pain in the shoulder area for at least 3 months and up to one year. Patients with a pain score of 5 or higher as determined by the visual analogue scale.

Exclusion criteria:

Full thickness tear in the supraspinatus tendon or Massive rupture in other rotator cuff tendons History of surgery and implants in the shoulder area History of steroid injection in the shoulder joint during the last six months Rheumatoid arthritis Diabetes Neurological disorders Hook-shaped acromion Cases such as tumor, pregnancy, malignant tissue, infection, heat disturbance and people who have undergone radiotherapy in the last 6 months

Age

From **20 years** old to **40 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to maintain the balance of the number of samples in the two groups and the homogeneity of the samples in the groups, we first divide the patients into four homogeneous classes based on age, sex and location of injury. Then, using the permutation block method, patients are randomly assigned to two treatment groups.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Blinding will be done for the participant, evaluator and data analyzer. Patients will be randomly divided into two groups. Low power and high power laser will be used in the intervention. Patients will not know which treatment group they are in. The evaluation is also performed by a person who is not aware of the patients in each group. Finally, we provide the groups to the statistical analyzer as a blind.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Beheshti University of Medical Sciences

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No. 7, west zayande rod Ave, north shirazi Ave, mollasadra Ave, vanak square

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1991613651

Approval date

2021-10-11, 1400/07/19

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.425

Health conditions studied**1****Description of health condition studied**

partial tear of supraspinatus tendon

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Supraspinatus tendon thickness, Echogenicity of supraspinatus tendon

Timepoint

Before intervention, after 10 treatment sessions, eight weeks after the end of the treatment sessions follow up

Method of measurement

Secondary outcomes

1

Description

Pain intensity

Timepoint

Before intervention, after 10 treatment sessions, eight weeks after the end of the treatment sessions follow up

Method of measurement

Based on visual analogue scale

2

Description

Shoulder abduction and adduction rang of motion

Timepoint

Before intervention, after 10 treatment sessions, eight weeks after the end of the treatment sessions follow up

Method of measurement

Using full circle goniometry

3

Description

Shoulder flexion and extension rang of motion

Timepoint

Before intervention, after 10 treatment sessions, eight weeks after the end of the treatment sessions follow up

Method of measurement

Using full circle goniometry

4

Description

Shoulder internal and external rotation rang of motion

Timepoint

Before intervention, after 10 treatment sessions, eight weeks after the end of the treatment sessions follow up

Method of measurement

Using full circle goniometry

5

Description

Shoulder pain and disability

Timepoint

Before intervention, after 10 treatment sessions, eight weeks after the end of the treatment sessions follow up

Method of measurement

Using Shoulder pain and Disability index questionnaire

Intervention groups

1

Description

Intervention group: Intervention group: At the beginning of the treatment session, people undergoing cold therapy were placed on the shoulder area for 10 to 15

minutes using an ice pack. Then, in the first group, citing the World Laser Therapy Association (WALT) on the properties of the most effective low-power laser parameters in supraspinatus tendinopathy, under low-power IR laser therapy with a wavelength of 810 nm are significant. According to the proposed WALT protocol, the laser is applied at 2 to 3 points at the site of supraspinatus muscle tendon insertion and the former acromial space, with a high energy content of 4 gels per square meter, and generally 12 joules of energy during treatment. The patient's position is sitting and the hand is in the adduction position during the laser application. Pendulum exercises and range of motion improvements from the initial sessions, and isometric strengthening exercises from the fifth session, were added to the treatment program. In order to observe safety during laser treatment, although the risk of eye injury is small, precautions for using the laser are observed.

Category

Rehabilitation

2

Description

Intervention group: Intervention group: At the beginning of the treatment session, people undergoing cryotherapy are placed on the shoulder region for 10 to 15 minutes using an ice pack. In this group, a laser with a power of 8 watts, energy of 12 joules per square centimeter and total energy of 10,000 joules will be used for about 15 minutes. The percussion of each pulse will be 150 microseconds and the frequency of 30 Hz in the first and third phases and the frequency of 25-25 Hz in the second phase will be used in an area of 25 cm² during the three phases. The initial phase is applied in front of the shoulder joint line, with 850 mJ of energy per shot and at a frequency of 30 Hz. Total energy applied in this phase is equal to 4000 joules. In the second phase, the energy of each pulse is equal to 350 mJ and with a frequency of 20-25 Hz in front and behind the shoulder joint line. The total energy of this phase is equal to 4000 joules. In the third phase, which is applied in the same place as the first phase as well as the deltoid muscle areas, a total energy of 2000 joules is radiated. In general, the time required for laser treatment in all three phases of treatment will be about 15 minutes. And how to use the laser is rapid manual scanning. A spacer with a diameter of 35 mm will also be used to ensure a constant distance between the applicator and the skin during laser treatment. The patient's position during the laser application is sitting with the affected hand in the adduction position. Pendulum exercises and range of motion improvements from the initial sessions, and isometric strengthening exercises from the fifth session are added to the treatment program. In order to observe safety during laser treatment, although the risk of eye injury is small, precautions for using the laser are observed.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

physiotherapy clinic of school of rehabilitation of
Shahid Beheshti University of Medical science

Full name of responsible person

Ali khoshdel

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

3rd Floor, Medical Faculty, Next to the Taleghani
hospital, Evin, Shahid Chamran highway

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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

Shahid Beheshti University of Medical Sciences

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ali Khoshdel

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

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Full name of responsible person

Abbas Rahimi

Position

Professor

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Ph.D.

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available