Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 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)
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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
Street address
No. 7, west zayande rod Ave, north shirazi Ave, mollasadra Ave, vanak square
City
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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

Ultrasonography imaging

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 goniometery

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 goniometery

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 goniometery

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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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