

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the Effects of High-Power Laser and Exercise Therapy on Supraspinatus Tendon Tear and Glenohumeral Joint Kinetics and Kinematics: Randomized Clinical Trial

Protocol summary

Study aim

Investigating the effect of high-power laser and exercise therapy on supraspinatus tendon tear and glenohumeral joint kinetics and kinematics

Design

This study is a single-blind randomized controlled clinical trial. The study will be conducted on two treatment and control groups of women and men, each group will include 23 people, with incomplete rupture of the supraspinatus tendon diagnosed by an orthopedic doctor and in the age range of 40-60 years. A group of 23 healthy people will also be evaluated to compare the parameters with the normal state.

Settings and conduct

This study will be done in Tarbiat Modares University in tehran and sampling will be done in the Orthopedic Clinic of Shafa Yahyayan Hospital in tehran. All evaluations, including ultrasound, electromyography, movement analysis, which are performed before and 48 hours after the last treatment session, will be done by an examiner who is blind to the grouping. Treatment in both treatment and sham groups will be done 10 sessions and 3 times a week.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1-3 cm tear in the supraspinatus tendon Age between 40-60 years Exclusion criteria: • Tears in other components of the rotator cuff with or without supraspinatus injury • Injury caused by exercise

Intervention groups

10 sessions of high-power laser therapy and exercise therapy and placebo laser and exercise therapy in Sham group, and healthy group

Main outcome variables

Strength of muscle groups, pain, Shoulder pain and disability index questionnaire, ultrasound evaluation, evaluation of muscle activity pattern, kinetic and kinematic variables will be done during the examination

up to 80 degrees.

General information

Reason for update

Providing additional information

Acronym

IRCT registration information

IRCT registration number: **IRCT20180406039203N2**

Registration date: **2024-01-28, 1402/11/08**

Registration timing: **prospective**

Last update: **2026-07-04, 1405/04/13**

Update count: **1**

Registration date

2024-01-28, 1402/11/08

Registrant information

Name

Zohre Zaki

Name of organization / entity

Tarbiat modares university

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 3595

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-19, 1402/11/30

Expected recruitment end date

2025-06-20, 1404/03/30

Actual recruitment start date

2024-02-19, 1402/11/30

Actual recruitment end date

2025-05-20, 1404/02/30

Trial completion date

2025-07-13, 1404/04/22

Scientific title

Evaluation of the Effects of High-Power Laser and Exercise Therapy on Supraspinatus Tendon Tear and Glenohumeral Joint Kinetics and Kinematics: Randomized Clinical Trial

Public title

The effect of high-power laser on supraspinatus tendon tear

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range: 40-60 years Body mass index 25-30 The presence of an incomplete tear of 1-3 cm in the supraspinatus according to MRI The positiveness of Drop Arm tests: empty can test, external rotation delay sign, champagne toast Having reading and writing literacy at the cycle level Moderate pain intensity based on Visual analogue scale 35-74 mm Arm circumference size cm 1.28-4.29

Exclusion criteria:

The unwillingness of people to continue treatment for any reason Tears in other components of the rotator cuff with or without supraspinatus injury Use of non-steroidal and steroidal anti-inflammatory drugs Injection in the shoulder in 3 months before the study Receiving physiotherapy treatments in 3 months before the study Damage caused by exercise The existence of a neurological disease that leads to muscle weakness or reduced range of motion History of systemic diseases such as: rheumatoid arthritis, diabetes, severe cardiovascular disease, history of shoulder surgery Presence of any shoulder pathology that leads to shoulder kinematic change Contraindications for laser use: pregnancy, epilepsy, pacemaker, cancer Dissemination of pain from the neck More than 12 months have passed since the onset of their symptoms

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **28**

Actual sample size reached: **69**

Randomization (investigator's opinion)

Randomized

Randomization description

Web-based randomization and masking through sealed envelopes will be used. First, the website <http://www.graphpad.com/quickcalcs/index.cfm> will be

used to create a random sequence. Sealed opaque envelopes are used to hide the random allocation. Envelopes with aluminum wrappers (in order to make the contents of the envelopes unclear), preparation and each of the randomly created sequences are recorded on a card and the cards are placed inside the envelopes in order. Finally, the envelope door The letters are glued and placed in a box in order. At the time of registration of the participants, based on the order of entry of eligible participants into the study, one of the envelopes will be opened and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)

Single blinded

Blinding description

Data collection will be done by an experimenter who is not aware of the grouping. The participants were also blinded to the intervention groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tarbiat Modares University

Street address

Jalal Al Ahmad

City

Tehran

Province

Tehran

Postal code

14115-111

Approval date

2023-10-22, 1402/07/30

Ethics committee reference number

IR.MODARES.REC.1402.122

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

Supraspinatus tendon partial thickness tear

ICD-10 code

M75.1

ICD-10 code description

Rotator cuff tear or rupture, not specified as traumatic

Primary outcomes

1

Description

Supraspinatus tendon tear size

Timepoint

Before and 48 hours after end of treatment

Method of measurement

The tear size is measured by ultrasound

2

Description

glenohumeral superior translation

Timepoint

Before and 48 hours after end of treatment

Method of measurement

Superior translation of the humeral head is measured by the motion analysis system.

Secondary outcomes

1

Description

pain

Timepoint

pre-treatment, before 5th session and 48 hours post treatment

Method of measurement

By visual analogue scale

2

Description

muscle groups strength

Timepoint

pre and 48 hours post treatment

Method of measurement

By hand held dynamometer

3

Description

pain and function

Timepoint

pre and 48 hours post treatment

Method of measurement

By shoulder and pain disability index

4

Description

EMG activity pattern, Root mean square

Timepoint

pre and 48 hours post treatment

Method of measurement

by electromyography system

5

Description

angular speed

Timepoint

pre and 48 hours post treatment

Method of measurement

by motion analysis system

6

Description

angular acceleration

Timepoint

pre and 48 hours post treatment

Method of measurement

by motion analysis system

7

Description

torque

Timepoint

pre and 48 hours post treatment

Method of measurement

by motion analysis system

Intervention groups

1

Description

Intervention group: K-laser will be used in this study. The treatment will be done 3 times a week for 10 sessions. In the first 3 sessions, the total energy will be 2478 joules, the average power will be 9 watts and the maximum power will be 20 watts. In the last 7 sessions, the total energy will be 4678 joules.

Category

Rehabilitation

2

Description

Control group: The treatment will be done 3 times a week for 10 sessions. Lasers are off in all meetings.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Shafa yahyaian Hospital

Full name of responsible person

Morteza Nakhaei Amroodi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tarbiat Modares University

Full name of responsible person

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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

Tarbiat Modares University

Proportion provided by this source

100

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

Tarbiat Modares University

Full name of responsible person

Zohreh Zaki

Position

Ph.D. candidate

Latest degree

Master

Other areas of specialty/work

Physiotherapy

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Full name of responsible person

Roya Ravanbod

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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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