Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the effect of high-power laser and Meloxicam in improving shoulder joint function and pain of patients with rotator cuff tendinopathy

Protocol summary

Study aim

Determining the effect of high-power laser on improving shoulder pain and movement in patients with rotator cuff tendinopathy

Design

A clinical trial with the control group, with parallel groups, double-blind, randomized, phase 3 on 42 patients

Settings and conduct

This randomized double-blind clinical trial study is performed in Al-Zahra and Kashani hospitals of Isfahan. In this study, 42 patients with rotator cuff tendinopathy will be included in the study and will be randomly divided into two groups. Patients in the first group will be treated only with high-power laser and patients in the second group will be treated with meloxicam tablets. The pain intensity and improvement in shoulder movement will then be assessed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with unilateral rotator cuff tendinopathy, previous normal radiograph of the shoulder, age range of 18-65 years, duration of symptoms less than 3 months, no other therapeutic intervention during the last 3 months such as steroid injection into the Shoulder joint or physiotherapy, the absence of contraindications to laser, consent to participate in the study. Exclusion criteria included having a history of surgery, having a fracture near the shoulder, severe direct or indirect trauma injuries, generalized disorders of the musculoskeletal system or neurological disorders, having underlying diseases, drug abuse, inability to communicate and cognitive impairment.

Intervention groups

Patients in both groups are instructed in exercises that strengthen the rotator cuff muscles and the shoulder girdle, with repetitions 3 times a day and 3 sets each time for 20 seconds. Then in the intervention group, high-power laser is performed in 10 sessions and 3 sessions per week. In the control group, meloxicam 15 mg is given once a day for 2 weeks.

Main outcome variables

Pain; Shoulder joint function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N52**
Registration date: **2022-05-12, 1401/02/22**
Registration timing: **prospective**

Last update: **2022-05-12, 1401/02/22**
Update count: **0**

Registration date

2022-05-12, 1401/02/22

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-22, 1401/03/01

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effect of high-power laser and Meloxicam in improving shoulder joint function and pain of patients with rotator cuff tendinopathy

Public title
The effect of high-power laser in the recovery of patients with rotator cuff tendinopathy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with unilateral rotator cuff tendonitis Previous normal radiograph of the shoulder Age between 18 and 65 years Symptoms last less than 3 months Failure to perform any other therapeutic intervention during the last 3 months such as steroid injection into the shoulder joint or physiotherapy No contraindications to performing lasers Satisfaction to participate in the study

Exclusion criteria:
History of surgery Having a fracture near the shoulder Severe direct or indirect injuries following traction Generalized disorders of the musculoskeletal system or nervous disorders Having underlying diseases (including hypertension, coagulation disorders, heart disease, liver disease, kidney disease, cancer) drug abuse Inability to communicate and cognitive impairment

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
The method is permuted block randomization. In this way, at first using online software (sealedenvelope), a sequence of random numbers will be created and by the same software, the generated numbers will be divided into 7 blocks of size 6. Which is an equal number in each block will be 3 items from the intervention group and 3 items from the control group. So by using each block, 3 patients (equally) will be assigned to each group.

Blinding (investigator's opinion)
Double blinded

Blinding description
Due to the different nature of the intervention in the two groups, the Care provider is aware of the type of intervention in each group. But the patient is not aware of the difference in treatment between the two groups. Also, the Outcome assessor and data analyzer of the two groups will not have information.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City
Isfahan

Province
Isfehan

Postal code
8179964167

Approval date
2022-04-07, 1401/01/18

Ethics committee reference number
IR.MUI.MED.REC.1401.005

Health conditions studied

1

Description of health condition studied
Rotator cuff tendinopathy

ICD-10 code
M75.11

ICD-10 code description
Incomplete rotator cuff tear or rupture not specified as traumatic

Primary outcomes

1

Description
Pain

Timepoint
Before, immediately and three months after the intervention

Method of measurement
Visual Analog Scale (VAS)

Secondary outcomes

1

Description
Shoulder joint function
Timepoint
Before, immediately and three months after the intervention
Method of measurement
Disabilities of the Arm, Shoulder and Hand outcome Measure (DASH)

Intervention groups

1

Description
Intervention group: After reducing the patient's pain, the patient is taught the exercises that strengthen the rotator cuff muscles and the shoulder girdle by repeating 3 times a day and 3 sets each time for 20 seconds. Patients are then treated with a high-power laser. So that, in the first stage, a slow scan (100 square cm2/minute) is performed along the rotator cuff tendons with an average of 10-15 J/cm2, which is the maximum energy received in this stage is 3000 J. In the second stage, on the painful points of the muscles around the shoulder and the joint line in the front, back, and outside of the joint, and on the patient's acromioclavicular joint, 10-15 J/cm2 are applied at each point and the maximum energy received in this stage is 2000 J. The output power of each wavelength will be set to 810 by 3 watts and output by 1.5 W, wavelength 910 by 300 Wand output by 0.1 W, wavelength 1064 by 2 watts and output by 1 W. The pulse frequency is set to 6,000 and the duty cycle to 50%, with a total output power of 2.6 W. The number of laser sessions for each patient will be 10 alternating sessions of 3 sessions per week.
Category
Other

2

Description
Control group: After reducing the patients' pain, the patient is taught the exercises that strengthen the rotator cuff muscles and the shoulder girdle by repeating 3 times a day and 3 sets each time for 20 seconds. Patients will then be given 15 mg of meloxicam tablets with food once daily for 2 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Raziye Maghroori
Street address
Hezar Jarib Street.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3620 2020
Email
maghroori@mui.ac.ir
Web page address

2

Recruitment center
Name of recruitment center
Kashani Hospital
Full name of responsible person
Razieh Maghroori
Street address
Physical Medicine and Rehabilitation Department, Kashani Hospital, Kashani Street.
City
Isfahan
Province
Isfehan
Postal code
8183983434
Phone
+98 31 3233 0091
Email
maghroori@mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mansour Siavash Dastjerdi
Street address
Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 8597
Email
dean@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

No

Title of funding source
Isfahan University of Medical Sciences

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
Esfahan University of Medical Sciences

Full name of responsible person
Razieh Maghroori

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Physical Medicine

Street address
Physical and Rehabilitation Department, Kashani Hospital, Kashani St., Isfahan

City
Isfahan

Province
Isfehan

Postal code
8183983434

Phone
+98 31 3233 0091

Email
maghroori@mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Razieh Maghroori

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Physical Medicine

Street address
Physical and Rehabilitation Department, Kashani Hospital, Kashani St., Isfahan

City
Isfahan

Province
Isfehan

Postal code
8183983434

Phone
+98 31 3233 0091

Email
maghroori@mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Hosein Mohammadi Berimanloo

Position
Non-faculty specialist physician

Latest degree
Specialist

Other areas of specialty/work
Physical Medicine

Street address
Physical and Rehabilitation Department, Kashani Hospital, Kashani St., Isfahan

City
Isfahan

Province
Isfehan

Postal code
8183983434

Phone
+98 31 3233 0091

Email
Hoseinmohammadi753@gmail.com

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
There is no further information

Study Protocol
No - There is not 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
No - There is not 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