

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effects of laser therapy on pain, range of motion and muscle thickness in subjects with adhesive capsulitis

Protocol summary

Study aim

1. Determining and comparing the mean of pain in subjects with adhesive capsulitis before, after five sessions, after ten sessions treatments and one month later 2. Determining and comparing the mean of abduction and external rotation in subjects with adhesive capsulitis before, after five sessions, after ten sessions treatments and one month later 3. Determining and comparing the mean of supraspinatous rest thickness in subjects with adhesive capsulitis before, after five sessions, after ten sessions treatments and one month later 4. Determining and comparing the mean of supraspinatous scaption 60 degree thickness in subjects with adhesive capsulitis before, after five sessions, after ten sessions treatments and one month later

Design

Randomized controlled clinical trial with factorial groups and double blinded

Settings and conduct

The rationale for this research is to determine the effects of laser therapy on pain, range of motion and muscle thickness in patients with adhesive capsulitis. This will be done in Poursina Hospital and neither patients nor examiners know the grouping and treatment procedures.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 16 to 60 years. Adhesive capsulitis diagnosis: According to orthopedic physician assessment; Patients with pain duration between 3-9 months. Exclusion criteria: Patients with pain duration less than 3 months. Patients with adhesive capsulitis which shoulder range of motion not affected. Patients with humerus, clavicle and scapula fractures. Patients with history of cervical and shoulder surgery, or capsular and tendon surgery. Patients with complete soft tissue tear such as tendons and labrum. Patients with referral pain from neck. Addict or pregnant individuals. Patients that took part in physiotherapy program about four weeks ago. Patients with history of rheumatoid diseases such as rheumatoid arthritis. Patients with history of

diabetes and other inflammatory, articular and myofascial diseases Patients that laser therapy is contraindicated due to tumor or hemorrhage Professional athletics

Intervention groups

Control group receive routine physical therapy treatments and intervention group receive routine physical therapy as well as laser therapy

Main outcome variables

Shoulder pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170516034003N2**

Registration date: **2018-02-01, 1396/11/12**

Registration timing: **prospective**

Last update: **2018-02-01, 1396/11/12**

Update count: **0**

Registration date

2018-02-01, 1396/11/12

Registrant information

Name

Kamran Ezzati

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-19, 1396/11/30

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of laser therapy on pain, range of motion and muscle thickness in subjects with adhesive capsulitis

Public title

The effects of laser therapy on pain and muscle thickness

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Adhesive capsulitis diagnosis: According to orthopedic physician assessment Patients with pain duration between 3-9 month

Exclusion criteria:

Patients with adhesive capsulitis which shoulder range of motion not affected. Patients with humerus, clavicle and scapula fractures Patients with complete soft tissues tear such as tendons and labrum Patients with history of diabetes and other inflammatory, articular and myofascial diseases Patients that laser therapy is contraindicated due to tumor or hemorrhage

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were assigned simple randomly by randomized numerical table between 1 to52 numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients in both groups receive routine physiotherapy and laser therapy is performed in just one group. Treatment is done by health care staff who are not aware of the grouping and only implement the treatment protocol. The evaluation is done by one of the researchers who does not know about the treatment

performed on patients.

Placebo

Not used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

Ethics committee of Guilan University of Medical Sciences

Street address

5th floor, Central office of Guilan University of Medical Sciences, Namjoo St., Rasht, Iran

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Postal code

۴۱۹۳۷۱۳۱۹۴

Approval date

2018-01-13, 1396/10/23

Ethics committee reference number

IR.GUMS.REC.1396.434

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

Adhesive capsulitis

ICD-10 code

M75.0

ICD-10 code description

Adhesive capsulitis of shoulder

Primary outcomes**1****Description**

Visual Analogue Scale

Timepoint

Before intervention, After five sessions treatments, After ten sessions treatments, one month follow-up

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

Shoulder range of motion with goniometer

Timepoint

Before intervention, After five sessions treatments, After ten sessions treatments, one month follow-up

Method of measurement

Goniometer

2

Description

Muscle thickness by sonography

Timepoint

Before intervention, After five sessions treatments, After ten sessions treatments, one month follow-up

Method of measurement

sonography

Intervention groups

1

Description

Intervention group: Interventions in this group include: 1) Infrared therapy for 20 minutes: The Infrared bulb is positioned at a distance of 50 cm from the shoulder of the individual. The patient will feel mild heat. 2- Treatment with TENS type brief for 20 minutes. In this method, four electrodes on the sides of the shoulder will be used. The frequency used varies from 3 to 120 Hz, and the patient will feel the electrical current, along with the muscle vibrations. 3- Exercise for strengthening muscle should include five exercises from the third to the tenth sessions twice daily. 4. Laser therapy: In this study, a laser with a wavelength of 905 nm, an energy density of 8 J / cm², a power of 50 mW in 10 points of the shoulder including 3 points on the anterior capsule, 3 points on the posterior capsule, 2 points on the root of the C5 nerve and the two points on the axillary region. The radiation time will be 91s for each point.

Category

Rehabilitation

2

Description

Control group: Interventions in this group include: 1) Infrared therapy for 20 minutes: The Infrared bulb is positioned at a distance of 50 cm from the shoulder of the individual. The patient will feel mild heat. 2- Treatment with TENS type brief for 20 minutes. In this method, four electrodes on the sides of the shoulder will be used. The frequency used varies from 3 to 120 Hz, and the patient will feel the electrical current, along with the muscle vibrations. 3- Exercise for strengthening muscle should include five exercises from the third to the tenth sessions twice daily.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Poursina hospital

Full name of responsible person

Kamran Ezzati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Guilan 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

Guilan University of Medical Sciences, Deputy of Research

Full name of responsible person

Sosan Komaei

Position

Bachelor of science

Latest degree

Bachelor

Other areas of specialty/work

Medical Education

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Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Sharing is done after the end of the study. The total potential data can be shared after unidentifications of individuals.

When the data will become available and for how long

Start the access period 6 months after publishing the results

To whom data/document is available

Researchers working in universities

Under which criteria data/document could be used

Researchers working in universities

From where data/document is obtainable

Adress: Physiotherapy section, Block 2, , Poursina
hospital, Namjoo St, Rasht

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

A written request for data from the relevant university
with the name and academic degree of the researcher

Comments