Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

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

Protocol summary

Study aim

1. Determining and comparing the mean of pain in 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 done in poursina hospital and neither patients no examiner know the grouping and treatments 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 month. 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 tissues tear such as tendons and labrum. Patients with referral pain form neck. Addict or pregnant individuals. Patients that took part in physiotherapy program about during 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 capslitis

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
City
Rasht
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Guilan
Postal code
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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 / cm 2, 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

Guilan University of Medical Sciences

Full name of responsible person

Shadman nemati

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http://www.gums.ac.ir/research

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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Assistant professor

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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 publicating 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