

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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 examiner 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)

##### Phone

+98 13 3369 0099

##### Email address

kamranezzati@gums.ac.ir

##### 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 to 52 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

**Province**

Guilan

**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 / cm<sup>2</sup>, 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

##### **Street address**

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

##### **City**

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##### **Province**

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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

##### **Street address**

Deputy of Research, Opposite to Azodi Stadium, Namjoo St, Rasht, Iran

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##### **Email**

Research@gums.ac.ir

##### **Web page address**

<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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## Person responsible for updating data

### Contact

**Name of organization / entity**

Guilan University of Medical Sciences

**Full name of responsible person**

Kamran Ezzati

**Position**

Assistant

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

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**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

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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 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**