

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Effects of Laser Acupuncture on Myofascial Pain Syndrome-a Randomised Controlled Trial on Female Subjects

#### Protocol summary

##### Study aim

The present study aimed to evaluate the therapeutic effects of low-level laser on acupuncture points in patients with MPS

##### Design

Randomized Controlled Single-blind clinical trial study

##### Settings and conduct

60 women with MPS were randomly assigned to two groups of 30. They were measured at baseline, the 5th and 10th sessions, and one month after the treatment with first physiotherapist. They underwent 10 sessions of low level laser ,for 15 minutes and were held every other day with second physiotherapist.

##### Participants/Inclusion and exclusion criteria

20-60-year-old women with MPS were selected through convenience sampling. Patients were only included if they had all or most well-identified symptoms of MPS. According to reliable rheumatology resources, include pain, spasms, sensitivity to stress, active trigger point, joint stiffness, muscle weakness, and motor limitation. In addition, the presence of active trigger points in the trapezius (upper fibers) was another necessity for entering the study. Patients were excluded if they had symptoms of fibromyalgia. Subjects with history of herniated discs, fractured neck or cervical vertebrae, surgery, radiculopathy, and myelopathy were also excluded. Moreover, individuals who had taken non-steroidal anti-inflammatory drugs or pain killers during the two-week period prior to treatment were not included.

##### Intervention groups

The participants were randomly allocated to two groups of 30 using a table of random numbers. The first group (treatment group) received laser acupuncture, the second group (control group) received off laser

##### Main outcome variables

Pain intensity during rest and exercise, range of motion

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190413043266N1**

Registration date: **2019-07-01, 1398/04/10**

Registration timing: **retrospective**

Last update: **2019-07-01, 1398/04/10**

Update count: **0**

##### Registration date

2019-07-01, 1398/04/10

##### Registrant information

##### Name

Hajar Sarami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3443 0615

##### Email address

hajarsarrami@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2009-08-16, 1388/05/25

##### Expected recruitment end date

2010-02-14, 1388/11/25

##### Actual recruitment start date

2009-08-01, 1388/05/10

##### Actual recruitment end date

2010-02-04, 1388/11/15

##### Trial completion date

2010-02-14, 1388/11/25

##### Scientific title

The Effects of Laser Acupuncture on Myofascial Pain Syndrome-a Randomised Controlled Trial on Female Subjects

#### Public title

The Effects of Laser Acupuncture

#### Purpose

Other

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patients were only included if they had all or most well-identified symptoms of MPS in the neck. According to reliable rheumatology resources, these symptoms include pain, spasms, sensitivity to stress, active trigger point, joint stiffness, muscle weakness, and motor limitation. In addition, the presence of active trigger points in the trapezius (upper fibers) was another necessity for entering the study.

##### Exclusion criteria:

Patients were excluded if they had symptoms of fibromyalgia in physical examination. Subjects with history of herniated discs, fractured neck or cervical vertebrae, surgery, radiculopathy, and myelopathy were also excluded. Moreover, individuals who had taken non-steroidal anti-inflammatory drugs or pain killers during the two-week period prior to treatment were not included.

#### Age

From **20 years** old to **60 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

- Participant
- Outcome assessor

#### Sample size

Target sample size: **60**

Actual sample size reached: **60**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

The participants were randomly allocated to two groups of 30 using a table of random numbers.

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

The physiotherapist, who was unaware of patient groupings, completed a questionnaire. He then assessed patients. The other physiotherapist performed 10 laser therapy sessions for the treatment groups with the laser. The same procedure was followed in the control group while the laser system was off. Similar conditions were considered for both groups.

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Esfahan University of Medical Sciences

##### Street address

Esabne Maryam Hospital Shamsabadi Ave

##### City

Esfahan

##### Province

Isfahan

##### Postal code

8199966131

#### Approval date

2009-08-16, 1388/05/25

#### Ethics committee reference number

IR.MUI.REC

## Health conditions studied

### 1

#### Description of health condition studied

Myofascial Pain Syndrome

#### ICD-10 code

M00-M99

#### ICD-10 code description

Diseases of the musculoskeletal system and connective tissue

## Primary outcomes

### 1

#### Description

Pain intensity during rest and exercise

#### Timepoint

Baseline, the 5th and 10th sessions, and one month after the treatment

#### Method of measurement

In order to measure pain intensity, the patients were asked to mark their pain during rest and exercise on a 10-cm linear visual analogue scale (VAS).

### 2

#### Description

The range of motion

#### Timepoint

Baseline, the 5th and 10th sessions, and one month after the treatment

#### Method of measurement

The active range of motion of the neck using a goniometer.

### 3

#### **Description**

Pressure sensitivity

#### **Timepoint**

Baseline, the 5th and 10th sessions, and one month after the treatment

#### **Method of measurement**

Pressure sensitivity was assessed using a mechanical pressure algometer

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Treatment group: Low-level laser (830 nm, 1.5 J, 30 mw) was applied on 13 Aqupuncture points (C7and SI3, LU7, GB21, GB34, GB39, UB10 bilaterally) with contact way. This group received exercise therapy. The sessions were held every other day and lasted for 15 minutes. An Enraf-Nonius Endolaser 476 (the Netherland) with 100% continuous output and vertical contact was used.

#### **Category**

Treatment - Devices

#### 2

#### **Description**

Control group: off laser aqupuncture received with contact way same point with treatment group. This group received exercise therapy. The sessions were held every other day and lasted for 15 minutes.

#### **Category**

Treatment - Devices

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

Isa-Ibn Maryam Hospital

##### **Full name of responsible person**

Sayed Mohsen Mirbod

##### **Street address**

Esfahan university

##### **City**

Esfahan

##### **Province**

Isfahan

##### **Postal code**

8174673461

##### **Phone**

+98 31 3792 5041

##### **Fax**

+98 31 3668 7270

##### **Email**

mirbod@rehab.mui.ac.ir

#### **Web page address**

<http://jrrs.mui.ac.ir/index.php/jrrs/article/view/137>

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Esfahan University of Medical Sciences

##### **Full name of responsible person**

Sayed Mohsen Mirbod

##### **Street address**

Esfahan university hezar jerib Ave

##### **City**

Esfahan

##### **Province**

Isfahan

##### **Postal code**

8174673461

##### **Phone**

+98 31 3792 5000

##### **Fax**

+98 31 3668 7270

##### **Email**

mirbod@rehab.mui.ac.ir

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

<https://rehab.mui.ac.ir/gph/90>

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Esfahan 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**

Sayed Mohsen Mirbod

##### **Position**

Associate professor

##### **Latest degree**

Master

##### **Other areas of specialty/work**

Physiotherapy

##### **Street address**

Esfahan university, hezar jrib Ave

**City**

Esfahan

**Province**

Isfahan

**Postal code**

۸۱۷۴۶۷۳۴۶۱

**Phone**

+98 31 3792 5000

**Fax**

+98 31 3668 7270

**Email**

mirbod@rehab.mui.ac.ir

**Web page address**<http://rehab.mui.ac.ir/gph/90>**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Sayed Mohsen Mirbod

**Position**

Associate professor

**Latest degree**

Master

**Other areas of specialty/work**

Physiotherapy

**Street address**

Esfahan university, hezar jrib Ave

**City**

Esfahan

**Province**

Isfahan

**Postal code**

۸۱۷۴۶۷۳۴۶۱

**Phone**

+98 31 3792 5000

**Email**

mirbod@rehab.mui.ac.ir

**Web page address**<http://rehab.mui.ac.ir/gph/90>**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Hajar Sarami

**Position**

BMS

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiotherapy

**Street address**

No 3, Elahie bld, Jaber Ave, Esfahan city

**City**

Esfahan

**Province**

Isfahan

**Postal code**

8138986352

**Phone**

+98 31 3443 0615

**Fax****Email**

hajarsarrami@gmail.com

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**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

**Title and more details about the data/document**

eshterak

**When the data will become available and for how long**

no

**To whom data/document is available**

no

**Under which criteria data/document could be used**

no

**From where data/document is obtainable**

no

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

no

**Comments**