

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

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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

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Esfahan university

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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

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

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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

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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