

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The effectiveness of low level laser therapy in comparison with exercise and medication on pain and disability indices of shoulder and neck in patients with myofascial pain syndrome in upper trapezius area

Protocol summary

Study aim

Myofascial pain syndrome is common in the trapezius muscle. The purpose of this study is to compare the effect of laser therapy with therapeutic exercises and medication on the treatment of symptoms of patients with myofascial pain syndrome in trapezius muscle.

Design

A single-blind randomized controlled clinical trial with a parallel group design of 50 patients, enrolled between January 2012 and January 2013, and followed for one month

Settings and conduct

The 50 patients who referred to physical medicine clinics and rehabilitation centers in Isfahan from 2012 to 2013 were enrolled in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria include clinical diagnosis of myofascial pain syndrome in upper trapezius muscle, willingness to participate in the study, VAS > 5 (moderate and severe) and duration of pain above one month. exclusion criteria include history of neck fracture or surgery, myelopathy or neck radiculopathy, mental illness or cognitive impairment, oral or intravenous use of opioids and corticosteroids, pregnancy, and coagulation disorders.

Intervention groups

In this study, 25 participants will be assigned to medication and exercise group and 25 in the laser-medication-exercise therapy group. Patients in both groups will similarly receive medication (NSIAD) and stretching. Stretching exercises will be given 3 times a day for 30 seconds. All participants will be treated with medication and stretching for 2 weeks. In the first group, every 25 people will continue to treat stretching and medication. In the second group, 25 patients undergo 10 sessions (three times a week) of low-power laser therapy plus stretching exercises and medication.

Main outcome variables

The amount of pain based on visual analogue scale (VAS)
Neck Disability Index (NDI) Shoulder pain disability index (SPDI)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180212038706N1**

Registration date: **2018-02-20, 1396/12/01**

Registration timing: **retrospective**

Last update: **2018-02-20, 1396/12/01**

Update count: **0**

Registration date

2018-02-20, 1396/12/01

Registrant information

Name

Sadegh Baradaran Mahdavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3236 0339

Email address

isrc_adm@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2012-01-01, 1390/10/11

Expected recruitment end date

2013-01-01, 1391/10/12

Actual recruitment start date

2012-04-20, 1391/02/01

Actual recruitment end date

2013-04-21, 1392/02/01

Trial completion date

empty

Scientific title

The effectiveness of low level laser therapy in comparison with exercise and medication on pain and disability indices of shoulder and neck in patients with myofascial pain syndrome in upper trapezius area

Public title

The effect of low-level laser therapy on myofascial pain syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Diagnosis of myofascial pain syndrome in upper trapezius muscle VAS > 5 (severe and moderate) Pain for more than one month The desire to participate in the study

Exclusion criteria:

History of neck spine fracture or neck surgery Myelopathy or neck radiculopathy Mental illness or cognitive impairment Oral or intravenous administration of opioid or corticosteroid Pregnancy Blood coagulation disorders

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **50**

Actual sample size reached: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random allocation: In this study, a specific code will be given to each of the individuals who are eligible for inclusion and exclusion criteria. Then 25 people will be allocated in the group of medication and therapeutic exercises and 25 people in the group of medication, therapeutic exercises and laser therapy via sortition.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the main executor is considered as a physician who knows the goals of the study and the types of treatments. The patients know their treatment, but they will not be aware of how the treatments will be compared. The statistical consultant does not know the two methods of treatment and the name of the patients. Therefore, this study is a single blind clinical trial.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Isfahan University of Medical Sciences

Street address

Close to Negin building, Ahmadih alley, Taleghani St

City

Isfahan

Province

Isfahan

Postal code

8136833691

Approval date

2012-01-01, 1390/10/11

Ethics committee reference number

392364

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

Myofascial pain syndrome

ICD-10 code

M79.1

ICD-10 code description

Myalgia

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

The amount of pain

Timepoint

Before starting the study, immediately after treatment and one month after the end of treatment

Method of measurement

Visual Analogue Scale (VAS)

2**Description**

Neck disability index

Timepoint

Before starting the study, immediately after treatment and one month after the end of treatment

Method of measurement

Neck Disability Index (NDI)

3

Description

Shoulder pain disability index

Timepoint

Before starting the study, immediately after treatment and one month after the end of treatment

Method of measurement

Shoulder Pain Disability Index (SPDI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Medication (NSIAD) and stretching exercises were given three times a day for 30 seconds for two weeks + 10 sessions of low-level laser therapy (three times a week)

Category

Treatment - Other

2

Description

Control group: Medication (NSIAD) and stretching exercises were given three times a day for 30 seconds for two weeks

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Somayeh Andalib

Street address

Sofeh Blvd

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

alzahra@mui.ac.ir

2

Recruitment center

Name of recruitment center

Kashani hospital

Full name of responsible person

Somayeh Andalib

Street address

Kashani St

City

Isfahan

Province

Isfahan

Postal code

۸۱۸۳۹۸۳۳۳۴

Phone

+98 31 3233 0091

Email

Kashani@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Peiman Adibi

Street address

Hezar Jarib St

City

Isfahan

Province

Isfahan

Postal code

۸۱۷۴۶۷۳۴۶۱

Phone

+98 31 3668 0048

Email

Alzahra@mui.ac.ir

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

Sadegh Baradaran Mahdavi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

Close to Negin building, Ahmadih alley, Taleghani St

City

Isfahan

Province

Isfahan

Postal code

8136833691

Phone

+98 31 3236 0339

Fax

Email

sadegh.b.mahdavi@gmail.com

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

Close to Negin building, Ahmadih alley, Taleghani St

City

Isfahan

Province

Isfahan

Postal code

8136833691

Phone

+98 31 3236 0339

Fax

Email

sadegh.b.mahdavi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Sadegh Baradaran Mahdavi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

Close to Negin building, Ahmadih alley, Taleghani St

City

Isfahan

Province

Isfahan

Postal code

8136833691

Phone

+98 31 3236 0339

Fax

Email

sadegh.b.mahdavi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Sadegh Baradaran Mahdavi

Position

Resident

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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

In this study, information on the main outcomes and results of the study will be published. Currently, there is no plan for publishing other patient information, even in an unidentified manner.

When the data will become available and for how long

Since 2015

To whom data/document is available

Unlimited

Under which criteria data/document could be used

Using documentation with citation

From where data/document is obtainable

Download the article from the journal website or contact the corresponding author of the article

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

Download the article from the journal website or contact the corresponding author of the article

Comments