Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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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, Ahmadieh alley, Taleghani St
City
Isfahan
Province
Isfehan
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
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Province
Isfehan
Postal code
8174675731
Phone
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2

Recruitment center
Name of recruitment center
Kashani hospital
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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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Hezar Jarib St
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+98 31 3668 0048
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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
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Person responsible for updating data

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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
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