Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Comparison of the laser acupuncture and medication effect on pain of myofascial pain syndrome

Protocol summary

Study aim
The aim of this study is evaluating the effect of laser acupuncture on myofascial pain

Design
This randomized clinical trial with parallel control group will be done on the patients with myofascial pain dysfunction syndrome who will be referred to oral and Maxillofacial Department of Shiraz Dental Faculty and Emam Reza clinic during 2018-2019. The participants will be enrolled in two groups of intervention group (laser acupuncture+ methocarbamol) and control group (methocarbamol) randomly by block randomization. 20 patients will be enrolled in each groups.

Settings and conduct
Patients with myofascial pain dysfunction syndrome who refer to the maxillofacial department of Shiraz Dental School and Imam Reza Clinic are treated in a single-blind study with two parallel groups. In intervention group laser acupuncture+ methocarbamol and in control group methocarbamol will be prescribed for patients. Evaluator of the results is blind. The patients are not blind to the type of treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: The patients with myofascial pain dysfunction syndrome exclusion criteria: The patients with who are under anti-inflammatory and muscle relaxant since a month ago

Intervention groups
In intervention group: 20 participates in addition to receiving methocarbamol (Darupakhsh Company, Tehran, Iran) 500mg every 8 hours for 2 weeks, will receive 3 sessions of laser acupuncture in a week for 10 sessions as their treatment. in control group: No laser acupuncture will be done.20 patients will receive only methocarbamol 500mg (Darupakhsh Company, Tehran, Iran) every 8 hours for 2 weeks.

Main outcome variables
pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120101008585N11**
Registration date: **2022-01-01, 1400/10/11**
Registration timing: **registered_while_recruiting**

Last update: **2022-01-01, 1400/10/11**
Update count: **0**

Registration date
2022-01-01, 1400/10/11

Registrant information

Name
Fatemeh Lavaee
Name of organization / entity
Shiraz Dental School
Country
Iran (Islamic Republic of)
Phone
+98 71 1631 9309
Email address
lavaeef@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-22, 1400/10/01

Expected recruitment end date
2023-12-22, 1402/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the laser acupuncture and medication effect on pain of myofascial pain syndrome

Public title
The effect of laser acupuncture on pain of myofascial pain syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
the patients with myofascial pain dysfunction syndrome The patients who sign a written consent form.

Exclusion criteria:
The patients with any skin problems. The patients with other musculoskeletal diseases The patients with tempromandubular diseases The patients with rheumatologic diseases The patients with who are under anti-inflammatory since a month ago The patients with who are under muscle relaxant since a month ago The patients with who are under analgesic medication since a month ago

Age
From **15 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Each block with 4 allocations, consisting 2 allocation for intervention and 2 for control group will be considered. Six possible sequence of treatment allocation in each block will be listed and each one will be written on a card. Each time a block will be selected and the sequence of treatment will be registered until the treatment allocations become completed for all 40 participants (10 blocks). The randomization was performed by a methodologist. Allocation concealment will be done by the main researcher. On each 40 cards a sequence will be written and sealed. Pockets will be put in a box. A pocket will be allocated for each participant based on order of enrollment.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Shiraz University of Medical Sciences, Namazi square, Zand street, Shiraz, Iran ایران، شیراز، خیابان زند، میدان نمازی، دانشگاه علوم پزشکی شیراز

City
Shiraz

Province
Fars

Postal code
7186781559

Approval date
2019-06-09, 1398/03/19

Ethics committee reference number
IR.SUMS.REC.1398.555

Health conditions studied

1

Description of health condition studied
Myalgia

ICD-10 code
M79.1

ICD-10 code description
Myalgia

Primary outcomes

1

Description
pain

Timepoint
Day 0, 7, 14, 21 after starting acupuncture

Method of measurement
Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The participates in addition to receiving tab Methocarbamol 500mg (Darupakhsh Company, Tehran, Iran) every 8 hours for 2 weeks, will receive 3 sessions of laser acupuncture in a week for 10 sessions as their treatment. Low level laser (BTL-5110) with 830nm wavelength, 100mv power, 146Hz frequency and cross section of 0.1 cm2 will be used. The laser will irradiate on acupuncture points DU20, GB2, LI4, ST6,

ST7, SI18 on ashi point of spasmatic muscle.

Category

Treatment - Other

2

Description

Control group: The patients will receive only tab Methocarbamol 500mg (Darupakhsh Company, Tehran, Iran) every 8 hours for 2 weeks.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

recruitment center School of Dentistry, Shiraz University of Medical Sciences

Full name of responsible person

Dr.Fateme Lavaee

Street address

Shiraz Dental School, Ghasrdasht street, Shiraz

City

Shiraz

Province

Fars

Postal code

7186781559

Phone

+98 71 3626 3193

Email

lavaeef@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Rezaianzadeh

Street address

Shiraz university of Medical Sciences, Zand street, Iran

City

Shiraz

Province

Fars

Postal code

7186781559

Phone

+98 71 3626 3193

Email

lavaeef@sums.ac.ir

Grant name

Grant code / Reference number

97-01-03-18272

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Lavaee

Position

Assistant Professor of Oral and Maxillofacial Medicine Department

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Shiraz School of Dentistry, Ghasrdasht street, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7186781559

Phone

+98 71 3631 9309

Email

lavaeef@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Fatemeh Lavaee

Position

Assistant Professor of Oral and Maxillofacial Medicine Department

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Shiraz School of Dentistry, Ghasrdasht street, Shiraz, Iran

City
Shiraz
Province
Fars
Postal code
7186781559
Phone
+98 71 3631 9309
Email
lavaeef@sums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Fatemeh Lavaee
Position
Assistant Professor of Oral and Maxillofacial Medicine Department
Latest degree
Specialist
Other areas of specialty/work
Dentistry
Street address
Shiraz School of Dentistry, Ghasrdasht street, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7186781559
Phone
+98 71 3626 3193
Email
lavaeef@sums.ac.ir

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
All collected data will be shared after deidentification of participants.
When the data will become available and for how long
6 months after publication data will become available.
To whom data/document is available
The researchers in academic institutions
Under which criteria data/document could be used
The researchers in academic institutions can email the request and can have the data. All analyses can be done.
From where data/document is obtainable
The researchers in academic institutions can email (fatemeh.lavaee@yahoo.com) responsible person and request information Fatemeh Lavaee Tel: 09177029159-07136263193
What processes are involved for a request to access data/document
The researchers in academic institutions can email responsible person and request information
Comments