

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

Comparing the effect of 808nm low-level laser and dry needling in the treatment of trigger point in patients with MPDS

Protocol summary

Study aim

Comparison of the effect of 808 nm low-power laser and dry needling on treatment of trigger points in patients with myofascial pain syndrome (MPDS)

Design

A clinical trial has two groups of treatment with parallel randomized groups

Settings and conduct

A total of 42 who are having Myofascial Pain Syndrome (MPDS) and who have criteria for entering the study are selected. A clinical examination is conducted by a specialist assistant in oral diseases under the supervision of Professor of Oral Medicine. The pain status at the patient's trigger points is recorded based on the VAS criteria in the initial examination, called VAS1. Patients are randomly divided into two groups of 21 patients. In the two treatment groups, muscle trigger points are used, which requires finding trigger points in the muscles. Muscles that are commonly used in trigger therapy include temporalis, masseter, and external trigonoid. Low-power laser GA-AL-AS lasers with a wavelength of 808 nm and a power of 0.5 watts for 60 seconds, with a power of 30 J at any point of the trigger and in the form of a continuous wave. In the other group, treatment is performed by dry needle in muscle trigger points.

Participants/Inclusion and exclusion criteria

Entry requirements: Age over 18 years The presence of a trigger point in the temporal muscle and / or the external masseter and / or trigonoid that has been previously indicated by touch
Non-arrival conditions: Use of analgesics, muscle relaxants, anti-inflammatory drugs and benzodiazepines
Needle Phobia
Hemorrhagic disorders
Metabolic diseases (diabetes) and vascular.
Neurological disorders (Trigeminal neuralgia)- Pregnancy.
Receiving any treatment for temporomandibular joint disorder

Intervention groups

Trigger point therapy of low level laser 808 nm and dry

needling

Main outcome variables

Reducing pain in the muscle trigger points
Reduce the number of muscle trigger points

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190523043679N1**

Registration date: **2019-08-19, 1398/05/28**

Registration timing: **retrospective**

Last update: **2019-08-19, 1398/05/28**

Update count: **0**

Registration date

2019-08-19, 1398/05/28

Registrant information

Name

Azin Khodabakhshi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4604 3561

Email address

azinkhodabakhshi1992@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of 808nm low-level laser and dry needling in the treatment of trigger point in patients with MPDS

Public title

Treating muscle pain by low-power laser and dry needle

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age over 18 years The presence of a trigger point in the temporal muscle and / or the external master and / or trigoid that has already been marked with a touch

Exclusion criteria:

Use of analgesics, muscle relaxants, anti-inflammatory drugs and benzodiazepines Fear of the needle Bleeding disorders Metabolic (diabetes) and vascular diseases Neurological disorders (trigeminal neuralgia). Pregnancy Get any treatment for temporomandibular joint disorder

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Not randomized

Randomization description**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**

National Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Sardar St. South Jungle End of Sadra

City

Tehran

Province

Tehran

Postal code

6581864858

Approval date

2019-01-19, 1397/10/29

Ethics committee reference number

IR.SBMU.DRC.REC.1397.046

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

Myofascial pain syndrome

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

The amount of pain in the triage of the masticatory muscles

Timepoint

Before and after each treatment and after ten days and one month

Method of measurement

by VAS

2**Description**

Maximum opening of the mouth without pain

Timepoint

Before and after each treatment and after ten days and one month

Method of measurement

By the ruler, the distance between the anisal edges of the anterior teeth is measured

3**Description**

Number of muscle trigger points

Timepoint

Before and after each treatment and after ten days and one month

Method of measurement

Clinical examination

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Treatment of muscle trigger points by low-power laser 808 nm

Category

Treatment - Devices

2

Description

Intervention group: Treating muscle trigger points by dry needling

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Shaheed Beheshti Department of Oral and Maxillofacial Medicine

Full name of responsible person

Maryam Baharvand

Street address

Evin Blvd Student, Shahid Beheshti Dental School

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2217 5350

Email

M.baharvand@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Evin, Blvd Student

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2217 5350

Email

M.baharvand@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Baharvand

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Evin, Student Blvd.

City

Tehran

Province

Tehran

Postal code

1983969411

Phone

+98 21 2217 5350

Email

M.Baharvand@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Maryam Baharvand

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Evin, Student Blvd, Shahid Beheshti Dental School

City

Tehran

Province

Tehran

Postal code

1983967411

Phone

+98 21 2217 5350

Email

M.baharvand@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azin Khodabakhshi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

Street address

Evin, Student Blvd, Shahid Beheshti Dental School

City

Tehran

Province

Tehran

Postal code

1983967411

Phone

+98 21 2217 5350

Email

Azinkhodabakhshi1992@gmail.com

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

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

No - There is not 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

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

All data and study data may be published

When the data will become available and for how long

Starting the access period from 2019

To whom data/document is available

Researchers working in academia and academia

Under which criteria data/document could be used

Researchers working in academia and academia

From where data/document is obtainable

Researchers working in academia and academics will email the person in charge and request information.

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

Researchers working in academia and academics will email the person in charge and request information.

Comments