

# 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

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**Email**

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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**

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

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

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Maryam Baharvand

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Professor

**Latest degree**

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**Other areas of specialty/work**

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**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**

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**Province**

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**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**