

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative Evaluation of Two Methods :Low Level Laser and Laser Acupuncture In Relieving Pain In Patients With Temporomandibular Disorders (A Randomized Clinical Trial)

#### Protocol summary

##### Summary

The aim of this study is to comparative the efficacy of low-level of laser therapy (LLL) and laser acupuncture in the management of pain in patients with temporomandibular joint disorders (TMD). In this randomized, double-blind clinical trial, 45 patients with TMD Will be divided randomly in three groups as follows: laser, laser acupuncture, and placebo. In the laser group, a pulsed 810-nm low-level laser (average power 200 mW) will be applied on the painful points twice a week for a 5-week period. In the placebo group, the treatment will be the same as that in the laser group, but without energy output. In the laser acupuncture group, a pulsed 810-nm low-level laser (average power 200 mW) will be used on acupuncture points (LI4, ST6, ST7) twice a week for a 5-week period. .The patients will be evaluated before laser therapy (T1), after five sessions of laser application (T2), at the end of treatment (T3), and 1 month after the last session (T4). Pain will be measured by using 10-cm Visual Analog Scale (VAS) scores and Maximum mouth opening. Lateral and protrusive mandibular movements , will be measured by the caliber of digitalis.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017010131710N1**  
Registration date: **2017-06-01, 1396/03/11**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-06-01, 1396/03/11

#### Registrant information

##### Name

Naeeme Daghestani

##### Name of organization / entity

Mashhad University of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 513882950115

##### Email address

daghestanin901@mums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Mashhad University of Medical Science

#### Expected recruitment start date

2016-11-28, 1395/09/08

#### Expected recruitment end date

2018-11-29, 1397/09/08

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparative Evaluation of Two Methods :Low Level Laser and Laser Acupuncture In Relieving Pain In Patients With Temporomandibular Disorders (A Randomized Clinical Trial)

#### Public title

Laser Therapy In Relieving Pain In Patients With Temporomandibular Disorders

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion Criteria: Patients with myogenic orofacial pain; limited mouth opening ; arthralgia ; difficulty chewing ; patients with pain in the myofascial and joint area and either during palpation or jaw movements Exclusion Criteria: Systemic diseases that affect temporomandibular joint ; patients who have received analgesics or anti-stress drugs during the last two weeks ; teeth pulpitis ; children ; pregnant women and nursing mothers ; epilepsy

**Age**

No age limit

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

No information

**Sample size**

Target sample size: 45

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Double blinded

**Blinding description****Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Mashhad Dental School

**Street address**

School of Dentistry, Vakilabad Blvd, Mashhad, Iran

**City**

Mashhad

**Postal code**

91735

**Approval date**

2016-12-28, 1395/10/08

**Ethics committee reference number**

IR.mums.sd.REC.1394.191

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

Temporomandibular Disorders

**ICD-10 code**

K07.6

**ICD-10 code description**

Temporomandibular joint disorders

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

pain

**Timepoint**

before treatment, third week,fifth week, tenth week

**Method of measurement**

Visual Analog Scale

**Secondary outcomes****1****Description**

measure of mouth opening

**Timepoint**

before treatment, third week,fifth week, tenth week

**Method of measurement**

caliber of digitalis

**2****Description**

measure of lateral and protrusive mandibular movements

**Timepoint**

before treatment, third week,fifth week, tenth week

**Method of measurement**

caliber of digitalis

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

In the laser group, a pulsed 810-nm low-level laser (average power 200 mW) are used on painful points two times a week for 5 weeks

**Category**

Treatment - Other

**2****Description**

In the laser acupuncture group, a pulsed 810-nm low-level laser (average power 200 mW) are used on acupuncture points (LI4 , ST6 , ST7 ) two times a week for 5 week

**Category**

Treatment - Other

**3****Description**

In the placebo group, the treatment is the same as that in the laser group, but without energy output

**Category**

Placebo

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Mashhad School of Dentistry

**Full name of responsible person**

Dr Azam Madani

**Street address**

Mashhad School of Dentistry

**City**

Mashhad

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Research and Technology Department of Mashhad  
University of Medical Sciences

**Full name of responsible person**

Dr Azam Madani

**Street address**

Mashhad Dentistry School

**City**

Mashhad

**Grant name**

951115

**Grant code / Reference number**

951115

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

Yes

**Title of funding source**

Research and Technology Department of Mashhad  
University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Mashhad Dentistry School

**Full name of responsible person**

Dr Azam Madani

**Position**

prosthodontist

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## **Sharing plan**

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

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*