

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The Efficacy of 940 nm Low-level Laser Therapy on Treatment of Patients with Myogenic Temporomandibular Joint Disorders

#### Protocol summary

##### Study aim

Effect of 940 nm LLLT on Myogenic TMD treatment

##### Design

Clinical trial with control group, parallel groups, triple blinded, randomized, phase 2 on 20 patients. The Rand function of Excel 2010 software was used for randomization.

##### Settings and conduct

20 patients with Inclusion criteria Who Refer to Urmia University Dental Public Health Ward, Enter to Study After Giving Informed Consent. For the intervention group in the light and laser clinic, 940 nm laser by Epic X biolase laser device will be used after calibration by the manufacturer, with output power of 300 mW in continuous mode, under dedicated control, With an energy density of 2.5 J / cm<sup>2</sup> at detected sensitive points for 20 seconds, 2 times per week, totalling 4 weeks, in direct contact technique to the painful points. Control group, In the same way the laser group, will be irradiated with a placebo laser (device with laser off). Patients, Researcher and Statist are blinded of sample assignment.

##### Participants/Inclusion and exclusion criteria

Entrance criterias: limited mouth opening or function presence of pain in masticatory muscles and/or TMJs, either in clenching or in jaw movements (TMD muscular disturbance (class Ia, Ib) or arthralgia (class IIIa).  
Exclusion criterias: patients who had major systemic disorders Patients with arthralgic temporomandibular joint disorders patients who received any form of treatment for TMD within the last month

##### Intervention groups

1. Intervention group: This group will be exposed to 940 nm laser with a power of 300 mW and to the temporomandibular joint area for 20 seconds two sessions per week for four weeks. 2. placebo group: In the same way, the placebo group will be exposed to Palsbo laser (device with laser off).

##### Main outcome variables

Patient satisfaction, Intensity of pain, The amount of mouth opening, Clicking sound, Deviation when opening the mouth.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180224038840N4**

Registration date: **2022-05-06, 1401/02/16**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-05-06, 1401/02/16**

Update count: **0**

##### Registration date

2022-05-06, 1401/02/16

##### Registrant information

##### Name

Seyyed Amir Seyyedi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3322 4288

##### Email address

seyyedi.a@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-21, 1401/02/01

##### Expected recruitment end date

2022-07-23, 1401/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
The Efficacy of 940 nm Low-level Laser Therapy on Treatment of Patients with Myogenic Temporomandibular Joint Disorders

**Public title**  
Effect of laser Therapy in Temporomandibular Joint Disorders

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
limited mouth opening or function presence of pain in masticatory muscles and/or TMJs, either in clenching or in jaw movements (TMD muscular disturbance (class Ia, Ib) or arthralgia (class IIIa).  
**Exclusion criteria:**  
patients who had major systemic disorders patients who received analgesic or anti-depressant over the last 2 weeks patients who had any bony abnormalities of the jaws such as arthropathy of the TMJ or rheumatoid arthritis Patients with psychological illness Patients with arthralgic temporomandibular joint disorders patients who received any form of treatment for TMD within the last month pregnant and feeding patients

**Age**  
No age limit

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Participant
- Investigator
- Data and Safety Monitoring Board

**Sample size**  
Target sample size: **20**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Patients will be randomly divided into two groups A and B, using Microsoft Excel software. In this way, for each new patient, an integer is randomly assigned from 1 to 20, and then in the software, each of these numbers will be randomly entered into one of the groups A or B.

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**  
Patients, Researcher and Statistician are blinded of sample assignment. Control group, In the same way the laser group, will be irradiated with a placebo laser (device with laser off) and Patients will not be aware of the type of radiation (device on or off). The Principal Investigator and statist do not know the nature of groups A and B. The examiner in charge of patient care is not aware of the type of patient grouping.

**Placebo**

Used

**Assignment**  
Parallel

**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**  
**Name of ethics committee**  
Ethics committee of Urmia University of Medical Sciences  
**Street address**  
Third floor, Jam Doctors Building, Madani Street 25713815555  
**City**  
urmia  
**Province**  
West Azarbaijan  
**Postal code**  
5713815555

**Approval date**  
2022-04-20, 1401/01/31

**Ethics committee reference number**  
IR.UMSU.REC.1401.016

## Health conditions studied

**1**

**Description of health condition studied**  
Tempromandibular Joint disorders

**ICD-10 code**  
M26.6

**ICD-10 code description**  
Tempromandibular Joint disorders

## Primary outcomes

**1**

**Description**  
The number of pain intensity on visual analogue scale (VAS)

**Timepoint**  
Measurement of pain intensity before the intervention, 2 weeks and 4 weeks after the start of the intervention and 1 month after the end of the treatment sessions.

**Method of measurement**  
visual analogue scale (VAS)

## Secondary outcomes

**1**

**Description**

amount of mouth opening

#### **Timepoint**

Measurement of pain intensity before the intervention, 2 weeks and 4 weeks after the start of the intervention and 1 month after the end of the treatment sessions

#### **Method of measurement**

Digital ruler

### **2**

#### **Description**

The amount of deviation while opening the mouth

#### **Timepoint**

Measurement of pain intensity before the intervention, 2 weeks and 4 weeks after the start of the intervention and 1 month after the end of the treatment sessions

#### **Method of measurement**

observation

### **3**

#### **Description**

Satisfaction with treatment

#### **Timepoint**

In the last session of laser treatment

#### **Method of measurement**

questionnaire

### **4**

#### **Description**

Click sound

#### **Timepoint**

Measurement of pain intensity before the intervention, 2 weeks and 4 weeks after the start of the intervention and 1 month after the end of the treatment sessions

#### **Method of measurement**

Hearing

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Intervention group: In the intervention group, 940 nm laser by Epic X biolase laser device (Ezlase; Biolase Technology, Inc., Irvine, CA, USA) will be used after review and calibration by the manufacturer, in the light and laser clinic, with output power of 300 mW in continuous mode, under dedicated control, With an energy density of 2.5 J / cm<sup>2</sup> at detected sensitive points for 20 seconds, 2 times per week, totalling 4 weeks, in direct contact technique to the painful points.

#### **Category**

Treatment - Other

### **2**

#### **Description**

Control group: Control group, In the same way the laser group, will be irradiated with a placebo laser (device with laser off). Patients will not be aware of the type of

radiation (device on or off).

#### **Category**

Placebo

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Alborz Clinic

##### **Full name of responsible person**

Seyyedi Seyyed Amir

##### **Street address**

Alborz Street, Alborz, UOrmia

##### **City**

Urmia

##### **Province**

West Azarbaijan

##### **Postal code**

5719736191

##### **Phone**

+98 44 3336 3600

##### **Email**

seyyediamir@yahoo.com

##### **Web page address**

<https://umsu.ac.ir/>

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Oroumia University of Medical Sciences

##### **Full name of responsible person**

professor Iraj Mohebbi

##### **Street address**

Alborz Dental Cilinic, Alborz Ave, Urmia Town

##### **City**

urmia

##### **Province**

West Azarbaijan

##### **Postal code**

571478734

##### **Phone**

+98 44 3223 4897

##### **Email**

seyyediamir@yahoo.com

##### **Web page address**

<https://umsu.ac.ir/>

#### **Grant name**

#### **Grant code / Reference number**

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

No

#### **Title of funding source**

Oroumia 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**

Oroumia University of Medical Sciences

**Full name of responsible person**

Zahra hajizadeh

**Position**

General Medicine Student

**Latest degree**

Master

**Other areas of specialty/work**

Dentistry

**Street address**

Alborz Dental Clinic, Alborz street, Urmia city

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5719736191

**Phone**

+98 44 3336 3600

**Email**

zahrahajizadeee19@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Seyyed Amir Seyyedi

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**

Alborz Dental Clinic, Alborz Ave, Urmia Town

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5756115111

**Phone**

+98 44 3336 3600

**Email**

seyyediamir@yahoo.com

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

Oroumia University of Medical Sciences

**Full name of responsible person**

Zahra hajizadeh

**Position**

General Medicine Student

**Latest degree**

Master

**Other areas of specialty/work**

Dentistry

**Street address**

Alborz Dental Clinic, Alborz street, Urmia city

**City**

Urmia

**Province**

West Azarbaijan

**Postal code**

5719736191

**Phone**

+98 44 3336 3600

**Email**

zahrahajizadeee19@gmail.com

**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**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Data on the main consequences can be shared

**When the data will become available and for how long**

Start the access period from 2023

**To whom data/document is available**

Researchesr

**Under which criteria data/document could be used**

Data are available for international researchs

**From where data/document is obtainable**

Visit urmia university of medical sciences.

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

The data can be accessed only from the oral health department of Urmia Dental School.

**Comments**