

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

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

#### Protocol summary

##### Study aim

Effect of 940 nm LLLT on TMD treatment

##### Design

Clinical trial with control group, parallel groups, three blinded, randomized, phase 2 on 34 patients. The Rand function of Excel 2010 software was used for randomization.

##### Settings and conduct

In this three-blind randomized clinical trial, 34 patients with symptoms of TMD will be randomly divided into intervention and placebo groups (n = 17). In the intervention group, 940 nm laser by Epic X biolase laser device (CA, USA) in a specialized light and laser clinic, with an output power of 300 mW with energy density of 2.5 J / cm<sup>2</sup>, in direct contact technique to the TMJ area for 20 seconds, Twice a week for 4 weeks. The groups will be evaluated in terms of pain intensity, rate of mouth opening, deviation during mouth opening and clicking sound.

##### Participants/Inclusion and 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 or arthralgia). 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 who received any form of treatment for TMD within the last month pregnant and feeding patients.

##### Intervention groups

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. 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: **IRCT20180224038840N3**

Registration date: **2022-04-23, 1401/02/03**

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

Last update: **2022-04-23, 1401/02/03**

Update count: **0**

##### Registration date

2022-04-23, 1401/02/03

##### Registrant information

##### Name

Seyyed Amir Seyyedi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3322 4288

##### Email address

seyedi.a@umsu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-03-21, 1401/01/01

##### Expected recruitment end date

2022-06-22, 1401/04/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
Effect of 940 nm Low-level Laser Therapy on Treatment of Patients with Tempromandibular Joint Disorders

**Public title**  
Effect of laser Therapy in Tempromandibular 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 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: **34**

**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 34, 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 Statist are blinded of sample assignment. Patients in both groups will not be aware of the effect of the laser. 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 2,

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5713815555

#### Approval date

2021-11-01, 1400/08/10

#### Ethics committee reference number

IR.UMSU.REC.1400.285

## 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: 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**

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#### **Postal code**

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#### **Phone**

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#### **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**

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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**

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**

Seyyed Amir Seyyedi

**Position**

Faculty

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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Emergency Alley, Resalat Boulevard

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Seyyed Amir Seyyedi

**Position**

faculty

**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**

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**

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**Phone**

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**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**

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**

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

**Data Dictionary**

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

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

34 patients referred to the diagnostic department of Alborz Dental Clinic who have signs and symptoms related to Temporomandibular Joint Disorders will be used in the study.

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

4 month

**To whom data/document is available**

Researchesr

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

Confidential

**From where data/document is obtainable**

Researchers

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

Permission from the Ethics Committee

**Comments**