

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the effect of low level laser therapy on pain and mouth opening in patients with temporomandibular joint disorders

#### Protocol summary

##### Study aim

Studying the effect of low-level laser therapy on pain and mouth opening in patients with temporomandibular joint disorders

##### Design

A controlled, parallel-group, double-blind, randomized, phase 3 clinical trial on 30 patients. Sealed opaque envelopes will be used for randomization.

##### Settings and conduct

The study will be conducted in the Department of Oral Medicine, Tabriz Faculty of Dentistry. The patient will be positioned semi-supine and irradiated with a laser for 40 seconds at 12 extra-oral points (5 points in the joint area and 7 in the muscles). The participant and the outcome assessor will be blinded to the group assignment.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients with temporomandibular joint disorders diagnosed by an oral medicine specialist. 2. Willingness to participate and providing informed consent. 3. Age range between 15-40 years. 4. Maximum vertical mouth opening less than 4 cm. 5. Presence of pain or clicking. Exclusion criteria: 1. Presence of systemic diseases with a history of cancer, radiotherapy, or chemotherapy. 2. Presence of a mass in the jaw, face, or neck area. 3. Presence of active infection in the jaw region. 4. Inferior alveolar nerve injury. 5. Depression. 6. Heart disease or cardiac pacemaker. 7. Rheumatoid arthritis. 8. Pregnancy. 9. Psychiatric disorders or seizures. 10. Use of anticholinergic drugs. 11. Unwillingness to participate or lack of patient cooperation. 12. Use of NSAIDs or analgesics during the last two weeks.

##### Intervention groups

Intervention group: They will receive supportive treatments and low-level diode laser. Control group: They will receive supportive treatments (warm compresses, muscle relaxant methocarbamol 500 mg every 8 hours, ibuprofen 400 mg every 12 hours, habit modification and stretching exercises) and inactive laser.

#### Main outcome variables

Pain level, mouth opening level

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20251004067495N1**

Registration date: **2025-12-05, 1404/09/14**

Registration timing: **prospective**

Last update: **2025-12-05, 1404/09/14**

Update count: **0**

##### Registration date

2025-12-05, 1404/09/14

##### Registrant information

##### Name

Rekar Salam Ali

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3336 3298

##### Email address

rekarr1311@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2025-12-11, 1404/09/20

##### Expected recruitment end date

2026-01-10, 1404/10/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effect of low level laser therapy on pain and mouth opening in patients with temporomandibular joint disorders

**Public title**

Evaluation of the effect of low level laser therapy on temporomandibular joint disorders

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Temporomandibular disorders diagnosed by an oral medicine specialist Having informed consent to participate in the study Age range: 15–40 years Vertical mouth opening less than 4 centimeters Presence of pain or clicking in Temporomandibular joint

**Exclusion criteria:**

Presence of systemic diseases with a history of cancer, radiotherapy, or chemotherapy Presence of a mass in the jaw, facial, or neck region Presence of an active infection in the jaw region Injury to the inferior alveolar nerve Cardiac disease, cardiac pacemaker Rheumatoid arthritis Pregnancy Mental health problems, seizure Depression Using anticholinergic drugs Patients unwillingness to participate and lack of cooperation Use of NSAIDs and analgesics in past 2 weeks

**Age**

From **15 years** old to **40 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **30**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Individuals will be randomly assigned to two groups using sealed opaque envelopes. First, 15 cards will be labeled "A" and 15 cards will be labeled "B." Then, a random assignment list will be generated using a random number table. In this way, for the numbers in the table, they will be extracted as two digits. If the number is less than 50, "A" will be assigned, and if it is more than 50, "B" will be assigned. The cards will be placed in opaque envelopes in random order and sealed. The envelopes will be placed in a box. At the start of participant registration, each participant will randomly select an envelope from the box and give it to the researcher in charge of randomization. The person in charge will open the envelopes and record the group assigned to each individual.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The study will be double-blind, and the patient and the person assessing the outcomes will not be aware of the groupings, and only the person applying the laser and the person responsible for randomization will be aware of the grouping. Also, the laser device will be turned on in the control group to make its sound, but the laser will not be activated, and since all patients' eyes will be closed to protect them from the laser light, they will not notice whether the laser is active or not.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics committee of Tabriz university of medical sciences faculty of dentistry

**Street address**

Golgasht

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614776

**Approval date**

2025-08-10, 1404/05/19

**Ethics committee reference number**

IR.TBZMED.REC.1404.376

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

Temporomandibular joint disorders

**ICD-10 code**

M26.6

**ICD-10 code description**

Temporomandibular joint disorders

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

The pain level

**Timepoint**

At the (first, fifth, and tenth) sessions.

**Method of measurement**

It will be assessed using the visual analogue scale, where

the most severe and unbearable pain is rated as 10, and complete absence of pain is rated as 0. The measurement will be performed at all three stages while the patient is at rest.

## 2

### **Description**

Mouth opening level

### **Timepoint**

At the (first, fifth, and tenth) sessions.

### **Method of measurement**

Maximum mouth opening will be measured using a ruler. The distance between the incisal edges of the upper and lower centrals will be measured at maximum opening. The measurement of maximum mouth opening will be repeated three times and the average of the results will be recorded.

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Supportive treatments for temporomandibular joint disorders including warm compresses, muscle relaxants Methocarbamol 500 mg every 8 hours, Ibuprofen 400 mg every 12 hours, habit modification and stretching exercises, along with laser therapy with a low-level diode laser with a wavelength of 980 nm.

#### **Category**

Rehabilitation

### 2

#### **Description**

Control group: Supportive treatments for temporomandibular joint disorders including warm compresses, muscle relaxants Methocarbamol 500 mg every 8 hours, Ibuprofen 400 mg every 12 hours, habit modification and stretching exercises, along with inactive laser.

#### **Category**

Rehabilitation

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Tabriz university of medical sciences

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

Hosein eslami

##### **Street address**

Golgasht

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Tabriz

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5166614776

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+98 41 3336 3298

##### **Email**

rekarr1311@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Tabriz University of Medical Sciences

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

Hosein eslami

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Golgasht

##### **City**

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##### **Email**

eslamihosein56@yahoo.com

#### **Grant name**

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

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

Yes

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

Tabriz 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**

Tabriz University of Medical Sciences

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

Hosein eslami

##### **Position**

Associate professor

##### **Latest degree**

Specialist

##### **Other areas of specialty/work**

Dentistry  
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## Person responsible for scientific inquiries

### Contact

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**Latest degree**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tabriz University of Medical Sciences  
**Full name of responsible person**  
Rekar Salam Ali  
**Position**  
Dental student

**Latest degree**  
Medical doctor  
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rekarr1311@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

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

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

18 months after the publication of the article resulting from the thesis

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

18 months after the publication of the article resulting from the thesis

### To whom data/document is available

Public

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

For therapeutic and research purposes

### From where data/document is obtainable

Through email with the project supervisor

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

Through email with the project supervisor

### Comments