

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

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

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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