Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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Name of organization / entity
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Iran (Islamic Republic of)
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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 fuculty 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
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
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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