Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effects of High-Power Laser Therapy and Ultrasound on Pain Reduction in Patients with Bilateral Temporomandibular Disorders (TMD): A single-blind randomized clinical trial

Protocol summary

Study aim
Comparison of the effects of high-power laser and ultrasound in reducing pain in patients with bilateral temporomandibular joint disorders (TMD)

Design
This study is a single-blind, randomized, within-subject (split-mouth) clinical trial in which each patient with bilateral TMD will receive high-power laser treatment on one side of the jaw and ultrasound on the opposite side. Fifteen eligible patients will be selected using a convenience sampling method.

Settings and conduct
This study will be conducted in the physiotherapy department of Dr. Shariati Hospital. It will be randomly assigned which side of the jaw (right or left) will be treated with laser and the opposite side with ultrasound. To maintain patient blinding, the type of intervention on each side of the jaw will not be recognizable to the patient, and the conditions of the two treatments will be made similar in terms of sensation, positioning, and probe contact for both sides. Each patient will receive 3 sessions per week for 3 weeks (total of 9 sessions).

Participants/Inclusion and exclusion criteria
Inclusion criteria: • People over 18 years of age. • Diagnosis of TMD by a maxillofacial specialist • Having bilateral temporomandibular joint pain with an intensity of at least 3 on the VAS scale • At least 3 months have passed since the onset of symptoms. Exclusion criteria: • Presence of signs of advanced degenerative joint disease (DJD) or osteoarthritis on TMJ joint radiographs • History of trauma or recent surgery in the temporomandibular joint area within at least the past 6 months • Having systemic diseases • Pregnancy

Intervention groups
In this study, each patient receives two interventions simultaneously in one session: one side of the jaw is treated with high-power laser and the opposite side is treated with ultrasound.

Main outcome variables
Calculating pain intensity using a visual analog scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260523069506N1**
Registration date: **2026-05-30, 1405/03/09**
Registration timing: **prospective**

Last update: **2026-05-30, 1405/03/09**
Update count: **0**

Registration date
2026-05-30, 1405/03/09

Registrant information

Name
Mohamad javad Seidi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-06-05, 1405/03/15

Expected recruitment end date
2026-09-21, 1405/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effects of High-Power Laser Therapy and Ultrasound on Pain Reduction in Patients with Bilateral Temporomandibular Disorders (TMD): A single-blind randomized clinical trial

Public title
High-Power Laser versus Ultrasound for Pain Management in Bilateral TMD: A Comparative Study"
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adults aged 18 years and older. Bilateral temporomandibular joint pain with a minimum intensity of 3 on the Visual Analog Scale (VAS). All temporomandibular joint disorders that result in pain in the TMJ capsule region, regardless of the underlying etiology, will be included in the study. Symptoms present for at least 3 months (chronicity ≥ 3 months Diagnosis of TMD established by an orofacial pain specialist / oral and maxillofacial specialist according to the Diagnostic Criteria for Temporomandibular Disorders (DC/TMD).
Exclusion criteria:
Presence of advanced degenerative joint disease (DJD) or osteoarthritis in the TMJ as evidenced by radiographic imaging. History of trauma or surgery in the temporomandibular joint region within the past 6 months. Active systemic or rheumatic diseases. Pregnancy Receiving or having received physiotherapy treatment for TMD.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **15**
More than 1 sample in each individual
Number of samples in each individual: **2**
A patient with bilateral TMD will randomly receive high-intensity laser on one side and ultrasound on the opposite side.
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
To maintain patient blinding, the type of intervention on each side of the jaw will not be recognizable to the patient, and the conditions for applying the two treatments in terms of feel, positioning, and probe contact will be made similar for both sides.
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee, Faculty of Dentistry, Tehran University of Medical Sciences
Street address
End of North Kargar Street, next to the Atomic Energy Organization, before reaching the Hakim Shargh Highway exit, Faculty of Dentistry, Tehran University of Medical Sciences
City
Tehran
Province
Tehran
Postal code
۱۴۳۹۹۵۵۹۹۱
Approval date
2026-05-19, 1405/02/29
Ethics committee reference number
IR.TUMS.DENTISTRY.REC.1405.023

Health conditions studied

1

Description of health condition studied
Temporomandibular Disorders
ICD-10 code
M26.6
ICD-10 code description
Temporomandibular joint disorders

Primary outcomes

1

Description
Pain level based on the Visual Analogue Scale scale
Timepoint
Assessments include pain intensity (Visual Analogue Scale) and are measured at three stages (before treatment, end of treatment, and one month afterward).
Method of measurement
Using the Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: First group (high-power laser): The G (Novinmed, Iran) Laser 885 device will be used with the following parameters: Pulsed mode, Peak power = 5 W; Average power = 1.5 W, applicator area 16 cm² :(area), Target dose: 30 J/cm² for the treatment area (based on the area of 16 cm², it is equivalent to 480 J of total energy to the area. Radiation time (calculation): According to the relationship Energy (J) = Average power (W) × time (s), the time required to deliver 480 J with an average power of 1.5 W is 5 minutes. Treatment method: The applicator is moved in a scan (continuous movement) over the mandibular ramus area and the area around the TMJ to cover the treatment area. Safety: Simultaneous use of protective glasses for the patient and the operator, recording the feeling of heat/burning before and after each session, recording and reporting any complications (redness, blisters, increased pain) and stopping the treatment if necessary.

Category
Treatment - Other

2

Description
Second intervention group: Second group (ultrasound): Ultrasound 215M (Novinmed, Iran) will be used with the following parameters: Frequency: 1 MHz, Intensity: 1.5 W/cm2, Mode: Continuous, Time: 5 minutes for each side. Treatment method: The probe with appropriate gel is moved in gentle circular motions over the masseter and temporal muscles to cover the entire treatment area. Safety: Continuous movement of the probe, use of sufficient gel, stop if you feel any unusual pain or discomfort, and record any complications.

Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Shariati Hospital

Full name of responsible person
Dr. Mohammad Javad Seidi

Street address
North Kargar Street, Jalal Al-Ahmad Intersection, Opposite the Faculty of Economics, Dr. Shariati Educational, Research and Treatment Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran 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
Tehran 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
Tehran University of Medical Sciences

Full name of responsible person
Mohamad javad Seidi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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