

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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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+98 21 2238 1695

Email address

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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 $\geq$ 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

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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
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Ramin Kordi

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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

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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