

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the effectiveness of low level laser therapy (LLLT) on the location of radiation to masticatory muscles and Temporomandibular joint /masticatory and cervical muscles and Temporomandibular joint in the treatment of Temporomandibular disorder patients

Protocol summary

Study aim

The objective of this study is to compare the effectiveness of Low-Level Laser Therapy (LLLT) using two different radiation protocols for managing Temporomandibular Disorders (TMD).

Design

This is a phase II/III, randomized, triple-arm, parallel, double-blind, placebo-controlled clinical trial. Simple randomization will be performed using a random number table. The study will be conducted on 30 patients.

Settings and conduct

Laser for 12 sessions (2 times a week). After the laser is finished, an occlusal splint (CAD/CAM) is made and prescribed for all groups

Participants/Inclusion and exclusion criteria

patients with TMD symptoms referring to the Department of Prosthodontics. Inclusion Criteria: Age between 20 and 50 years; diagnosis of TMD based on DC/TMD and RDC/TMD criteria; presence of orofacial pain, clicking or limitation of mandibular movement for more than 3 months Exclusion Criteria: Recent facial trauma; congenital or developmental jaw disorders; recent facial bone fractures; systemic musculoskeletal diseases; current or previous cancer; skin lesions at laser site; pregnancy; recent TMD treatment within the last month; psychiatric disorders; complete denture wearers; dental or periodontal pain

Intervention groups

Intervention 1: Low-level laser therapy (LLLT) applied to the masticatory muscles and the temporomandibular joint (TMJ). The laser is irradiated on trigger points of the masseter and temporal muscles and the TMJ area. Intervention 2: LLLT applied to the masticatory muscles, TMJ, and cervical muscles (SCM and trapezius). Control/Placebo Group: identical to the intervention groups, but the laser device is in "off" mode (no active

radiation). Only the red indicator light and the device's notification sound.

Main outcome variables

Treatment; Pain; Maximum mouth opening; Lateral jaw movements; Protrusive jaw movement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260131068714N1**

Registration date: **2026-06-03, 1405/03/13**

Registration timing: **registered_while_recruiting**

Last update: **2026-06-03, 1405/03/13**

Update count: **0**

Registration date

2026-06-03, 1405/03/13

Registrant information

Name

vida badrooj

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-06-03, 1405/03/13

Expected recruitment end date

2026-08-23, 1405/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of low level laser therapy (LLLT) on the location of radiation to masticatory muscles and Temporomandibular joint /masticatory and cervical muscles and Temporomandibular joint in the treatment of Temporomandibular disorder patients

Public title

Evaluation of the effectiveness of low level laser therapy (LLLT) on the location of radiation to masticatory muscles and Temporomandibular joint /masticatory and cervical muscles and Temporomandibular joint in the treatment of Temporomandibular disorder patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 20 and 50 years diagnosis of TMD based on DC/TMD and RDC/TMD criteria presence of orofacial pain, clicking or limitation of mandibular movement for more than 3 months

Exclusion criteria:

Recent facial trauma congenital or developmental jaw disorders recent facial bone fractures systemic musculoskeletal diseases current or previous cancer skin lesions at laser site pregnancy recent TMD treatment within the last month psychiatric disorders complete denture wearers dental or periodontal pain

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization Method: "Participants will be assigned to one of the three study groups using simple randomization based on a random number table."
Allocation Concealment: "To ensure allocation concealment, sequentially numbered, opaque, sealed envelopes will be used. These envelopes will be prepared by an individual not involved in the clinical treatment

and will only be opened after the participant's eligibility is confirmed and their informed consent is obtained, indicating their assigned group (Intervention 1, Intervention 2, or Placebo)

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is designed as a double-blind clinical trial. Furthermore, the clinical evaluator (the individual responsible for measuring pain scales and maximum mouth opening) will be kept blind to the group assignments. This trained evaluator will conduct all clinical examinations and data collection without knowledge of whether the patient belongs to the intervention groups (masticatory muscles and TMJ / masticatory, cervical muscles and TMJ) or the placebo group, thereby minimizing potential assessment bias."

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of shahid beheshti University of Medical Sciences

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No 18,Pasdaran,Third Neistan street, Rastovan Street

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Postal code

1944965114

Approval date

2026-06-02, 1405/03/12

Ethics committee reference number

IR.SBMU.DRC.REC.1404.064

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

temporomandibular disorder

ICD-10 code

M26.60

ICD-10 code description

Temporomandibular joint disorder, unspecified

Primary outcomes

1

Description

pain

Timepoint

Before the study, immediately after the laser therapy, and approximately 30 days after the completion of the laser therapy.

Method of measurement

visual scale analogue

2

Description

Amount of mandibular movement

Timepoint

Before the study, immediately after the laser therapy, and approximately 30 days after the completion of the laser therapy.

Method of measurement

International Association for Dental Research

3

Description

Maximum mouth opening

Timepoint

Before the study, immediately after the laser therapy, and approximately 30 days after the completion of the laser therapy.

Method of measurement

Distance between upper and lower incisors in two assisted and unassisted modes by ruler

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Laser irradiation at the location of the upper, middle, lower and temporal master muscles, including anterior points, and laser irradiation at the Temporomandibular joint, including anterior, superior, lateral, posterior points, and the trapezius muscle.

Category

Treatment - Other

2

Description

Intervention group: Laser irradiation at the location of the upper, middle, lower and temporal master muscles, including anterior points, and laser irradiation at the Temporomandibular joint, including anterior, superior, lateral, posterior points

Category

Treatment - Devices

3

Description

Control group: In similar conditions to the laser therapy group, only red light and laser warning sound will be used.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Dental School

Full name of responsible person

Vida Badrooj

Street address

Shahid Chamran Highway, Evin, Daneshjoo Blvd.,
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vice President for Research and Technology, Shahid
Beheshti Dental School

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بزرگراه شهید چمران، اوین، بلوار دانشجو، دانشکده دندانپزشکی
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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

20

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Vida Badrooj

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Position

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Position

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Latest degree

Medical doctor

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

A portion of the data, including information on key outcomes, needs to be shared

When the data will become available and for how long

Access period starts 3 months after results are published.

To whom data/document is available

It will be available only to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Requests for access to data can be made via email

From where data/document is obtainable

Via email: vidabadrooj55@gmail.com

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

Depending on the amount of data requested, it will take 6-9 months

Comments