Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

+98 21 2661 4752

Email address

vidabadrooj55@gmail.com

Recruitment status

recruiting

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
Street address
No 18,Pasdaran,Third Neistan street, Rastovan Street
City
Tehran
Province
Tehran
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., Faculty of Dentistry, Shahid Beheshti Dental University
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 2217 5351
Fax
+98 21 2240 3194
Email
DentIt@sbmu.ac.ir
Web page address
http://dentistry.sbmu.ac.ir/

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
Street address
بزرگراه شهید چمران، اوین، بلوار دانشجو، دانشکده دندانپزشکی دانشگاه علوم پزشکی شهید بهشتی
City
Tehran
Province
Tehran
Postal code
1983969411
Phone
+98 21 2217 5351
Fax
+98 21 2240 3194
Email
DentIt@sbmu.ac.ir

Web page address
http://dentistry.sbmu.ac.ir/
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
Street address
Tehran, third neyestan Ave,rastvan Ave, number 18
City
Tehran
Province
Tehran
Postal code
1944965114
Phone
+98 21 2661 4752
Fax
Email
vidabadrooj55@gmail.com

Person responsible for scientific 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
Street address
Tehran, third neyestan Ave,rastvan Ave, number 18
City
Tehran
Province
Tehran
Postal code
1944965114
Phone
+98 21 2661 4752
Fax
Email
vidabadrooj55@gmail.com

Person responsible for updating data

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
Street address
Pasdaran - Third Neistan Street - Rastavan Street - No. 18
City
Tehran
Province
Tehran
Postal code
1944965114
Phone
+98 21 2217 5350
Fax
+98 21 2240 3194
Email
DentIt@sbmu.ac.ir
Web page address
http://dentistry.sbmu.ac.ir/

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