

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Evaluation of the Effectiveness of Low Level Laser Therapy (LLLT) on the Location of Radiation to Masticatory Muscles and TMJ Masticatory Muscles in the Treatment of TMD Patients

Protocol summary

Spontaneous Pain; Pain During Function; Limited Range of Jaw Movements

Study aim

The Aim of This Study is to Investigate The Short-term and Long-term Therapeutic Effects of Low Level Laser along with The Use of Digital Occlusal Splints in the Treatment of TMD Patients.

Design

A Concealed, Randomized, Unblinded, Sham Controlled Clinical Trial With Two Parallel Groups design among 30 Patients. The rand function of Excel software was used for randomization.

Settings and conduct

The place of the study: Department of Dental Prostheses; Shahid Beheshti Dental School, Tehran; Population: TMD patients; Blinding: blinding was not done in this study.

Participants/Inclusion and exclusion criteria

Inclusions Criteria: Age of Patients Between 20 and 50 years; Diagnosis of TMD based on DC / TMD and RDC / TMD criteria) Exclusion Criteria: History of Recent Facial Trauma; Congenital or Developmental Disorders of The Jaw; History or Presence of Systemic Musculoskeletal Diseases; History or Presence of Cancer; Pregnancy; History of Previous Treatment of TMD During The Last Month; using Complete Dentures

Intervention groups

Intervention group 1: Low Level diode Laser Treatment; 12 Sessions; In 10 Points of The Masticatory Muscles For 10 Seconds in Each Point Bilaterally. Then Using The Digital Occlusal Splint for three months. Intervention group 2: Low Level diode Laser Treatment; 12 Sessions; In 18 Points of The Masticatory Muscles And TMJ For 10 Seconds in Each Point Bilaterally. Then Using The Digital Occlusal Splint for Three Months. Control group: Under The Same Conditions As The Laser Treatment Group, Only The Red Light And Laser Warning Sound Will be Used for 12 Sessions. Then Using The Digital Occlusal Splint for three months.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220613055160N1**

Registration date: **2022-07-11, 1401/04/20**

Registration timing: **prospective**

Last update: **2022-07-11, 1401/04/20**

Update count: **0**

Registration date

2022-07-11, 1401/04/20

Registrant information

Name

Leili Habibi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2217 5351

Email address

habibileila1366@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2022-11-22, 1401/09/01

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 TMJ Masticatory Muscles in the Treatment of TMD Patients

Public title
Using Low Level Laser in The Treatment of The TMD patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age between 20 and 50 years Diagnosis of TMD based on DC / TMD and RDC / TMJ criteria) Click problems, limitation in maximum mouth opening and chronic orofacial pain more than three months

Exclusion criteria:
History of Recent Trauma to The Face Congenital or Developmental Disorders of The Jaw History of Recent facial Bone Fractures History or Presence of Systemic Musculoskeletal Diseases History or Current Cancer History or Presence of Skin Lesions at The Laser Site Pregnancy History of Previous TMD Treatment History or Presence of Mental Disorders Complete Dentures Patients Presence of Toothache or Periodontal Lesions

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

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
The Rand Function of Excel Software was used for Randomization. The Allocation of Patients to 3 Treatment Groups is done in the form of Randomized Blocks. So that 5 Blocks of 6 are defined, and in Each of These Blocks, the Order of Treatments is generated randomly with the Excel Program. Patients receive Random Treatment in These Randomized Blocks in the Order of Referral.

Blinding (investigator's opinion)
Not blinded

Blinding description
Placebo

Used
Assignment

Parallel
Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Research of Dental School of Shahid Beheshti University of Medical Science

Street address

Shahid Beheshti Dental School; Shahid Beheshti University of Medical Sciences; Evin Blvd.

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2022-07-02, 1401/04/11

Ethics committee reference number

IR.SBMU.DRC.REC.1401.024

Health conditions studied

1

Description of health condition studied

Temporomandibular disorder

ICD-10 code

M26.6

ICD-10 code description

Temporomandibular joint disorders

Primary outcomes

1

Description

Intensity of spontaneous pain

Timepoint

Spontaneous Pain Measurement before the Study, 30 Days after the Completion of the Laser Therapy Period; 30 and 90 Days after Using the Digital Occlusal Splint

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Pain Intensity During function

Timepoint

Measurement of Pain During Function before the Study, 30 Days after the Completion of the Laser Treatment Period; 30 and 90 Days after Using Digital Occlusal Splint.

Method of measurement

Visual Analogue Scale

2

Description

Maximum Mouth Opening

Timepoint

Measurement of the Maximum Mouth Opening before the Study, 30 Days after the Completion of the Laser Treatment Period; 30 and 90 Days after Using Digital Occlusal Splint.

Method of measurement

Using a Ruler in millimeter Scale

3

Description

Mandibular Lateral Movements

Timepoint

Measurement of the Mandibular Lateral Movement before the Study, 30 Days after the Completion of the Laser Treatment Period; 30 and 90 Days after Using Digital Occlusal Splint.

Method of measurement

Using a Periodontal Probe in millimeter scale

4

Description

Mandibular Protrusive Movement

Timepoint

Measurement of the Mandibular Protrusive Movement before the Study; 30 Days after the Completion of the Laser Treatment Period; 30 and 90 Days after Using Digital Occlusal Splint.

Method of measurement

Using a Periodontal Probe in millimeter Scale

Intervention groups

1

Description

Intervention Group 1: 300mW Diode Laser Irradiation for 10 Seconds Bilaterally in the Upper, Middle and Lower Points of the Masseter Muscle; the Anterior Temporal Muscle and the Sternocleidomastoid Muscle

Category

Treatment - Devices

2

Description

Intervention Group 2: 300mW Diode Laser Irradiation for 10 Seconds Bilaterally in the Upper, Middle and Lower Points of the Masseter Muscle; the Anterior Temporal Muscle; the Sternocleidomastoid Muscle and the Superior, Inferior, Anterior and Posterior Points of the TMJ.

Category

Treatment - Devices

3

Description

Control group: In the Similar Conditions to the Laser Treatment Group, only Red Light and Laser Warning Sound will be used

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Dental Prosthesis, Shahid Beheshti Faculty of Dentistry

Full name of responsible person

Leili Habibi

Street address

Shahid Beheshti Faculty of Dentistry; Shahid Beheshti University of Medical Sciences; Daneshjoo Blvd; Evin 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

Afshin Zarghi

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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

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

Email

saratavakolizadeh@gmail.com

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Leili Habibi

Position

Postgraduate student of prosthodontics

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for general inquiries**Contact****Name of organization / entity**

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Sara Tavakolizade

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All Patient's Data Including Age, Sex and results

Research will be Shareable After Making Individuals Undistinguishable.

When the data will become available and for how long

At the Same Time as Publishing Results

To whom data/document is available

Researchers in Academic and Scientific Institutions

Under which criteria data/document could be used

Quantitative Analyzes on the Results are allowed

From where data/document is obtainable

Leili Habibi. 0098 9122512396. hiyam1365@yahoo.com

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

After Receiving E-mail from Applicant, it will Take up to one Month to send Documents.

Comments