

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of 940 nm Low-level Laser Therapy on Treatment of Patients with Temporomandibular Joint Disorders

Protocol summary

Study aim

Effect of 940 nm LLLT on TMD treatment

Design

Clinical trial with control group, parallel groups, three blinded, randomized, phase 2 on 34 patients. The Rand function of Excel 2010 software was used for randomization.

Settings and conduct

In this three-blind randomized clinical trial, 34 patients with symptoms of TMD will be randomly divided into intervention and placebo groups (n = 17). In the intervention group, 940 nm laser by Epic X biolase laser device (CA, USA) in a specialized light and laser clinic, with an output power of 300 mW with energy density of 2.5 J / cm², in direct contact technique to the TMJ area for 20 seconds, Twice a week for 4 weeks. The groups will be evaluated in terms of pain intensity, rate of mouth opening, deviation during mouth opening and clicking sound.

Participants/Inclusion and exclusion criteria

Inclusion criteria: limited mouth opening or function presence of pain in masticatory muscles and/or TMJs, either in clenching or in jaw movements (TMD muscular disturbance or arthralgia). Exclusion criteria: patients who had major systemic disorders patients who received analgesic or anti-depressant over the last 2 weeks patients who had any bony abnormalities of the jaws such as arthropathy of the TMJ or rheumatoid arthritis Patients with psychological illness patients who received any form of treatment for TMD within the last month pregnant and feeding patients.

Intervention groups

Intervention group: This group will be exposed to 940 nm laser with a power of 300 mW and to the temporomandibular joint area for 20 seconds two sessions per week for four weeks. In the same way, the placebo group will be exposed to Palsbo laser (device with laser off).

Main outcome variables

Patient satisfaction, Intensity of pain, The amount of mouth opening, Clicking sound, Deviation when opening the mouth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180224038840N3**

Registration date: **2022-04-23, 1401/02/03**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-23, 1401/02/03**

Update count: **0**

Registration date

2022-04-23, 1401/02/03

Registrant information

Name

Seyyed Amir Seyyedi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2022-06-22, 1401/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Effect of 940 nm Low-level Laser Therapy on Treatment of Patients with Tempromandibular Joint Disorders

Public title
Effect of laser Therapy in Tempromandibular Joint Disorders

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

limited mouth opening or function presence of pain in masticatory muscles and/or TMJs, either in clenching or in jaw movements (TMD muscular disturbance (class Ia, Ib) or arthralgia (class IIIa).

Exclusion criteria:

patients who had major systemic disorders patients who received analgesic or anti-depressant over the last 2 weeks patients who had any bony abnormalities of the jaws such as arthropathy of the TMJ or rheumatoid arthritis Patients with psychological illness patients who received any form of treatment for TMD within the last month pregnant and feeding patients

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Data and Safety Monitoring Board

Sample size
Target sample size: **34**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be randomly divided into two groups A and B, using Microsoft Excel software. In this way, for each new patient, an integer is randomly assigned from 1 to 34, and then in the software, each of these numbers will be randomly entered into one of the groups A or B.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Patients, Researcher and Statist are blinded of sample assignment. Patients in both groups will not be aware of the effect of the laser. The Principal Investigator and statist do not know the nature of groups A and B. The examiner in charge of patient care is not aware of the type of patient grouping.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

Third floor, Jam Doctors Building, Madani Street 2,

City

Urmia

Province

West Azarbaijan

Postal code

5713815555

Approval date

2021-11-01, 1400/08/10

Ethics committee reference number

IR.UMSU.REC.1400.285

Health conditions studied

1

Description of health condition studied

Tempromandibular joint disorders

ICD-10 code

M26.6

ICD-10 code description

Tempromandibular joint disorders

Primary outcomes

1

Description

The number of pain intensity on visual analogue scale (VAS)

Timepoint

Measurement of pain intensity before the intervention, 2 weeks and 4 weeks after the start of the intervention and 1 month after the end of the treatment sessions.

Method of measurement

visual analogue scale (VAS)

Secondary outcomes

1

Description

amount of mouth opening

Timepoint

Measurement of pain intensity before the intervention, 2 weeks and 4 weeks after the start of the intervention and 1 month after the end of the treatment sessions

Method of measurement

Digital ruler

2

Description

The amount of deviation while opening the mouth

Timepoint

Measurement of pain intensity before the intervention, 2 weeks and 4 weeks after the start of the intervention and 1 month after the end of the treatment sessions

Method of measurement

Observation

3

Description

Satisfaction with treatment

Timepoint

In the last session of laser treatment

Method of measurement

questionnaire

4

Description

Click sound

Timepoint

Measurement of pain intensity before the intervention, 2 weeks and 4 weeks after the start of the intervention and 1 month after the end of the treatment sessions

Method of measurement

Hearing

Intervention groups

1

Description

Intervention group: In the intervention group, 940 nm laser by Epic X biolase laser device (Ezlase; Biolase Technology, Inc., Irvine, CA, USA) will be used after review and calibration by the manufacturer, in the light and laser clinic, with output power of 300 mW in continuous mode, under dedicated control, With an energy density of 2.5 J / cm² at detected sensitive points for 20 seconds, 2 times per week, totalling 4 weeks, in direct contact technique to the painful points.

Category

Treatment - Other

2

Description

Control group: Control group, In the same way the laser group, will be irradiated with a placebo laser (device with laser off). Patients will not be aware of the type of radiation (device on or off).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alborz Clinic

Full name of responsible person

Seyyedi Seyyed Amir

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Alborz Street, Alborz, UOrmia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

professor Iraj Mohebbi

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Seyyed Amir Seyyedi

Position

Faculty

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for updating data

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General Medicine Student

Latest degree

Master

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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

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

Title and more details about the data/document

34 patients referred to the diagnostic department of Alborz Dental Clinic who have signs and symptoms related to Temporomandibular Joint Disorders will be used in the study.

When the data will become available and for how long

4 month

To whom data/document is available

Researchesr

Under which criteria data/document could be used

Confidential

From where data/document is obtainable

Researchers

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

Permission from the Ethics Committee

Comments