Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of 940 nm Low-level Laser Therapy on Treatment of Patients with Tempromandibular 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
Intrusion 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

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Iran (Islamic Republic of)

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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

Temporomandibular 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
professor Iraj Mohebbi
Street address
Alborz Dental Cilinic,Alborz Ave,Urmia Town
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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
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Other areas of specialty/work
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Person responsible for updating data

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zahrahajizadeee19@gmail.com

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 Tempromandibular 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