Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

The Efficacy of 940 nm Low-level Laser Therapy on Treatment of Patients with Myogenic Tempromandibular Joint Disorders

Protocol summary

Study aim

Effect of 940 nm LLLT on Myogenic TMD treatment

Design

Clinical trial with control group, parallel groups, triple blinded, randomized, phase 2 on 20 patients. The Rand function of Excel 2010 software was used for randomization.

Settings and conduct

20 patients with Inclusion criteria Who Refer to Urmia University Dental Public Health Ward,Enter to Study After Giving Informed Consent.For the intervention group in the light and laser clinic, 940 nm laser by Epic X biolase laser device will be used after calibration by the manufacturer,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. Control group, In the same way the laser group, will be irradiated with a placebo laser (device with laser off). Patients، Researcher and Statist are blinded of sample assignment.

Participants/Inclusion and exclusion criteria

Entrance criterias: 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 criterias: patients who had major systemic disorders Patients with arthralgic temporomandibular joint disorders patients who received any form of treatment for TMD within the last month

Intervention groups

1.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. 2.placebo group: 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: **IRCT20180224038840N4**
Registration date: **2022-05-06, 1401/02/16**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-06, 1401/02/16**
Update count: **0**

Registration date

2022-05-06, 1401/02/16

Registrant information

Name

Seyyed Amir Seyyedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3322 4288

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-07-23, 1401/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Efficacy of 940 nm Low-level Laser Therapy on Treatment of Patients with Myogenic Tempromandibular Joint Disorders

Public title

Effect of laser Therapy in Tempromandibular Joint Disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

limited mouth opening or functionpresence 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 with arthralgic temporomandibular joint disorders 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: **20**

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 20, 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 Statistician are blinded of sample assignment. Control group, In the same way the laser group, will be irradiated with a placebo laser (device with laser off) and Patients will not be aware of the type of radiation (device on or off). 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 25713815555

City

urmia

Province

West Azarbaijan

Postal code

5713815555

Approval date

2022-04-20, 1401/01/31

Ethics committee reference number

IR.UMSU.REC.1401.016

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: 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

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

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
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Zahra hajizadeh
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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
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Data on the main consequences can be shared
When the data will become available and for how long
Start the access period from 2023
To whom data/document is available
Researchesr
Under which criteria data/document could be used
Data are available for international researchs
From where data/document is obtainable
Visit urmia university of medical sciences.
What processes are involved for a request to access data/document
The data can be accessed only from the oral health department of Urmia Dental School.
Comments