

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Evaluation of therapeutic effect and placebo effect of low level laser therapy in temporomandibular disorders

Protocol summary

Study aim

evaluation of therapeutic and placebo effects of low level laser therapy for pain relief due to temporomandibular joint disorders

Design

randomized double blind, parallel clinical trial, 3 groups , whit control group, 15 participant in each groups (total :45), enrolled between September 2019 and September 2020

Settings and conduct

this study take place in Department of Oral Medicine and Orofacial Pain, Kerman School of Dentistry by pain specialist. Diagnostic Criteria for TMD (DC/TMD) Axis I use for diagnosis. patients and doctors will not aware of patients' tretment groups and just low level leaser device operator will be informed.

Participants/Inclusion and exclusion criteria

inclusion criteria: Myofascial pain (muscle trigger point), TMJ tenderness, limitation of mouth opening due to muscle pain or TMJ inflammation, ability of reading and writing to answer questionnaires, patient cooperation and compliance, men and women 15-60 years old
exclusion criteria: using corticosteroids and narcotics, mixed dentition, developmental deformity, current orthodontic, orthopedic appliance or splint therapy,dental carries which replicated patient's pain, partial or complete denture, pregnancy and breast feeding, history of pathological lesions in temporomandibular regions, history of chemotherapy and radiotherapy of head and neck, inability of answer to questionnaires, periodontal diseases, rheumatologic diseases, Degenerative Joint Disease TMJ

Intervention groups

group control: no intervention, patients fallow standard treatment protocol without Encounter by low level leaser therapy (LLLT). intervention group 1: use active LLLT for patients + standard treatment protocol intervention group 2: use inactive LLLT for patients + standard treatment protocol

Main outcome variables

Visual Analogue Scale (VAS), Total trigger point score, Maximum mouth opening, Joint sounds

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180602039951N1**

Registration date: **2019-09-15, 1398/06/24**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-15, 1398/06/24**

Update count: **0**

Registration date

2019-09-15, 1398/06/24

Registrant information

Name

sahar Mafi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 34 3211 8074

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-06, 1398/06/15

Expected recruitment end date

2019-12-06, 1398/09/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of therapeutic effect and placebo effect of low level laser therapy in temporomandibular disorders

Public title
Evaluation of therapeutic effect and placebo effect of low level laser therapy in temporomandibular disorders

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
acute and chronic myofascial pain (muscle trigger point) TMJ tenderness without degenerative diseases limitation of mouth opening due to muscle pain or TMJ inflammation ability of reading and writing to answer questionnaires patient cooperation and compliance men and women between 15-60 years old
Exclusion criteria:
using NSAID, corticosteroids, anti-convulsant, anti-psychotic, anti-depressant and narcotics mixed dentition developmental head and face deformity current orthodontic treatment, orthopedic appliance or splint therapy dental carries which replicated patient's pain in head and face partial or complete denture pregnancy and breast feeding history of pathological lesions in temporomandibular regions history of chemotherapy and radiotherapy of head and neck inability of answer to questionnaires periodontal diseases rheumatologic diseases Degenerative Joint Disease TMJ

Age
From **15 years** old to **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
randomization will be done by computer software, patients will be divided to 3 groups, receptionist will extract patient's group and pass it to operator in sealed envelop. patients and doctors that evaluate treatment result will not be informed of patient's groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
patients: Blind interviewer: Blind therapist: Blind low level leaser machine operator: informed receptionist will extract patient's group and pass it to operator in sealed

envelop. patients and their doctors will not informed. patients are blindfolded and beeping sound of machine is on for both groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
ethics committee of Kerman university of medical science
Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7618759689

Approval date
2018-03-12, 1396/12/21

Ethics committee reference number
IR.KMU.REC.1396.2420

Health conditions studied

1

Description of health condition studied
temporomandibular disorders

ICD-10 code
M26.6

ICD-10 code description
Temporomandibular joint disorders

Primary outcomes

1

Description
effect of low level leaser therapy on total trigger point score

Timepoint
Total trigger point score before intervention, and 1, 2, 3,4,5, weeks during intervention and one month after final intervention will be recorded

Method of measurement
head and neck muscles examination

2

Description

effect of low level laser therapy on jaw sounds

Timepoint

before intervention, and 1, 2, 3,4,5,weeks during intervention

Method of measurement

Stethoscope

3

Description

effect of low level laser therapy on jaw movement

Timepoint

before intervention, and 1, 2, 3,4,5,weeks during intervention

Method of measurement

ruler

4

Description

effect of low level laser therapy on visual analog scale

Timepoint

before intervention, and 1, 2, 3,4,5,weeks during intervention

Method of measurement

visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: gallium-aluminum-arsenide, 808nm , 300 mw, 3J/cm² , 10S 10 session (twice a week for 5 weeks), 4 points around temporomandibular joint and every muscle trigger point in head and neck.

Category

Treatment - Devices

2

Description

Intervention group: Intervention group 2 : using the same device that used in intervention group 1. Intervention in this group will be same as intervention group except that the device will be in active.

Category

Placebo

3

Description

Control group: patients in this group will not face low level laser therapy and will follow standard treatment protocol.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

orofacial Pain Department of Dentistry School of Kerman

Full name of responsible person

Goli Chamani

Street address

Shafa Boulevard, Kerman, Kerman Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dental School of Kerman University of Medical science

Full name of responsible person

Molouk Torabi

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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

Dental School of Kerman University of Medical science

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

Kerman University of Medical Sciences

Full name of responsible person

Sahar Mafi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Person responsible for updating data

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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

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

all collected deidentified IPD, IPD collected for the primary outcome measure only

When the data will become available and for how long

6 months after publication

To whom data/document is available

for people working in academic institutions or people working in businesses

Under which criteria data/document could be used

people working in academic institutions

From where data/document is obtainable

s.mafi@kmu.ac.ir Dr.Sahar Mafi

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

requests containing how the data will be used must be applied via Email. Citation in future publication is mandatory. Data will be sent within 3 months.

Comments