Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 leaser 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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s.mafi@kmu.ac.ir

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 leaser 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 leaser 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 leaser 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 leaser 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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Province
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Postal code
7618759689
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Email
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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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+98 34 3211 8074
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m_torabi@kmu.ac.ir
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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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