

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 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)

##### Phone

+98 34 3211 8074

##### Email address

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 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/cm<sup>2</sup> , 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

#### **City**

Kerman

#### **Province**

Kerman

#### **Postal code**

7618759689

#### **Phone**

+98 34 3211 9021

#### **Email**

s.mafi@kmu.ac.ir

## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Dental School of Kerman University of Medical science

#### **Full name of responsible person**

Molouk Torabi

#### **Street address**

Dental School of Kerman University of Medical science, Shafa Boulevard, Kerman, Kerman Province

#### **City**

Kerman

#### **Province**

Kerman

#### **Postal code**

7618759689

#### **Phone**

+98 34 3211 8074

#### **Email**

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

#### Street address

Shafa Boulevard, Kerman, Kerman Province

#### City

Kerman

#### Province

Kerman

#### Postal code

7618759689

#### Phone

+98 34 3211 9021

#### Email

s.mafi@kmu.ac.ir

## Person responsible for scientific 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

#### Street address

Jomhouri Boulevard, Shafa Boulevard, Kerman Province, Kerman,

#### City

Kerman

#### Province

Kerman

#### Postal code

7618759689

#### Phone

+98 34 3211 8074

#### Fax

#### Email

s.mafi@kmu.ac.ir

## Person responsible for updating data

### 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

#### Street address

Jomhouri Boulevard, Shafa Boulevard, Kerman Province, Kerman,

#### City

Kerman

#### Province

Kerman

#### Postal code

7618759689

#### Phone

+98 34 3211 8074

#### Fax

#### Email

s.mafi@kmu.ac.ir

## 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