

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison between the effect of physiotherapy and Laser Therapy on the management of temporomandibular joint disorders

#### Protocol summary

##### Study aim

Compare effectiveness of trans cutaneous electrical nerve stimulation(TENS) and low level laser therapy( LLLT) in temporomandibular joint disorder(TMD) patients who don't response to pharmacological therapy.

##### Design

Clinical trial with parallel group, single blind, Block randomized.

##### Settings and conduct

Patients referred to the Oral medicine Department of Shiraz Dental school, receive laser and TENS treatment by one person in block randomization method. The examiner who records the data, is blind.

##### Participants/Inclusion and exclusion criteria

"Inclusion criteria:Patients have pain in temporomandibular joint regions and muscles; with or without noise in joints ; with or without limitation in jaw movements" "Exclusion criteria: patient with systemic disease and medicine usage"

##### Intervention groups

"Intervention group1:TENS. TENS (NEURDYN) is applied for 8 consecutive sessions for 2 weeks, 20 minutes on painful muscle." "Intervention group 2: Laser. low-power laser (AZOR) is applied for 10 sessions, every other day, with a dose of 12 J / cm 2 on the muscle and joint."

##### Main outcome variables

Pain; Function

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130521013406N4**

Registration date: **2019-04-10, 1398/01/21**

Registration timing: **retrospective**

Last update: **2019-04-10, 1398/01/21**

Update count: **0**

##### Registration date

2019-04-10, 1398/01/21

##### Registrant information

###### Name

Fahimeh Rezazadeh

###### Name of organization / entity

Dental school of shiraz university of medical science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1628 9917

###### Email address

rezazadehf@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-09-23, 1397/07/01

##### Expected recruitment end date

2018-11-22, 1397/09/01

##### Actual recruitment start date

2018-09-23, 1397/07/01

##### Actual recruitment end date

2019-01-06, 1397/10/16

##### Trial completion date

2019-02-20, 1397/12/01

##### Scientific title

Comparison between the effect of physiotherapy and Laser Therapy on the management of temporomandibular joint disorders

##### Public title

Comparison between the effect of physiotherapy and Laser on the treatment of temporomandibular joint disorder

##### Purpose

Treatment

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Patients have pain in TMJ regions and muscles with or without noise in joints and with or without limitation in jaw movements

### **Exclusion criteria:**

Missing of five or more posterior teeth ( except for third molars) Systemic diseases

## **Age**

No age limit

## **Gender**

Both

## **Phase**

N/A

## **Groups that have been masked**

- Outcome assessor

## **Sample size**

Target sample size: **30**

Actual sample size reached: **30**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

The method is Block randomization . Each block with 4 allocations, consisting 2 allocation for intervention and 2 for control group will be considered. Six possible sequence of treatment allocation in each block will be listed and each one will be written on a card. Each time a block will be selected and the sequence of treatment will be registered until the treatment allocations become completed for all 30 participants (8 blocks). The randomization was performed by a methodologist. Allocation concealment will be done by the main researcher. On each 30 cards a sequence will be written and sealed. Pockets will be put in a box. A pocket will be allocated for each participant based on order of enrollment.

## **Blinding (investigator's opinion)**

Single blinded

## **Blinding description**

In this study, the examiner is blind. In this way, the examiner or data collector, during pain and joint function examination, is not aware of the type of treatment that patients receive when assessing pain and function. But the patient and the main investigator who applies the treatment, are not blind.

## **Placebo**

Not used

## **Assignment**

Parallel

## **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

## **Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

## **Street address**

Medical Science Building,Zand Street,Namazee Square,Shiraz

## **City**

Shiraz

## **Province**

Fars

## **Postal code**

71345-54213

## **Approval date**

2015-11-11, 1394/08/20

## **Ethics committee reference number**

93-01-03-8636

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Temporomandibular joint disorder

#### **ICD-10 code**

M25.8

#### **ICD-10 code description**

Other specified joint disorders

## **Primary outcomes**

### 1

#### **Description**

Pain

#### **Timepoint**

Each treatment session

#### **Method of measurement**

Visual analogue scale

### 2

#### **Description**

Function

#### **Timepoint**

Before and After the intervention

#### **Method of measurement**

Helkimo index

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

"Intervention group1: TENS" Physiotherapy with TENS (NEURDYN) equipment is performed for 8 sessions(4 consecutive days per week) within 2 weeks. Carbon electrodes (6.5×4.5cm) are placed on the tender and painful muscles with 75 HZ frequency and 0.75

millisecond pulse width for 20 minutes per session.

**Category**

Treatment - Devices

**2****Description**

"Intervention group2: Low level laser"Low-power lasers with Azore device apply every other day for 10 sessions, with a dose of 12 J / cm 2 on a temporal joint.

**Category**

Treatment - Devices

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Shiraz Dental School

**Full name of responsible person**

Khadijeh Hajian

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Shiraz dental school,Ghasrodasht Street,Ghom abad,Shiraz

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Ali hashemi

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hashemiba@sums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Khadijeh Hajian

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

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## Person responsible for updating data

### Contact

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Shiraz University of Medical Sciences

**Full name of responsible person**

Fahimeh rezazadeh

**Position**

Assistant professor

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**Other areas of specialty/work**

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Not applicable

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Not applicable

### Data Dictionary

Not applicable

### Title and more details about the data/document

Only part of the information, such as information on the main outcome or such this,, can be shared

### When the data will become available and for how long

Start the access period from 2019

### To whom data/document is available

Only for researchers working in academic and scientific institutions

### Under which criteria data/document could be used

For clinical use, it could be used through the responsible person .

### From where data/document is obtainable

Khadijeh hajian with phone number 09177025755

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

Once requested, it takes 3 to 6 months to access the data .

### Comments