

# 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<sup>2</sup> 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

#### Street address

Shiraz dental school,Ghasrodasht Street,Ghom abad,Shiraz

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7145-5231

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rezazadehf@sums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Full name of responsible person

Ali hashemi

#### Street address

Medical science building,Zand Ave.,Namazee Square,Shiraz

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#### Phone

+98 71 3233 4510

#### Email

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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hajiankh@sums.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shiraz University of Medical Sciences

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Fahimeh rezazadeh

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Assistant professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Dentistry

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## Person responsible for updating data

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Shiraz University of Medical Sciences

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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