Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

Street address
Shiraz dental school,Ghasrodasht Street,Ghom abad,Shiraz

City
Shiraz

Province
Fars

Postal code
7145-5231

Phone
+98 71 3628 9917

Email
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

City
Shiraz

Province
Fars

Postal code
71435-57321

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

Street address
Ghom abad,Ghasrodasht street,Shiraz

City
Shiraz

Province
Fars

Postal code
71545-57321

Phone
+98 987136249917

Email
hajiankh@sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Fahimeh rezazadeh

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

Street address
Ghom abad,Ghasrodasht Street,Shiraz

City
Shiraz

Province
Fars

Postal code

71745-57321

Phone

+98 71 3628 9917

Email

rezazadehf@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Fahimeh rezazadeh

Position

Assisstant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

Ghom abad,Ghasrodasht Street,Shiraz

City

Shiraz

Province

Fars

Postal code

72451-57321

Phone

+98 71 3628 9917

Email

rezazadehf@sums.ac.ir

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