Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative study of the effect of laser acupuncture and transcutaneous electrical nerve stimulation on pain reduction patients with myofascial pain dysfunction syndrome

Protocol summary

Study aim
Comparison of Needle Laser and physiotherapy Methods for Reducing Pain in Patients with Myofascial Pain Dysfunction Syndrome

Design
Clinical trials with two paralle groups, Non blind and randomized without placebo control

Settings and conduct
The project is conducted at the Department of Oral and Maxillofacial Diseases, College of Dentistry affiliated to Tehran University of Medical Sciences. We divide the patients into two groups randomly. The first group receives physiotherapy and the second group receives acupuncture laser.A total of 22 volunteers will participate in this study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People aged 18-60 years old; pain in temporomandibular joint. Non-Inclusion criteria: systemic articulo-muscular disorders

Intervention groups
Intervention group 1:Physiotherapy group in which 11 patients were treated with TENS device with 180 Hz frequency during 10 20-minute sessions .Intervention group 2: acupuncture group in which 11 patient were treated with diode laser with 940 nm and 0.5 w power.

Main outcome variables
Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20090914002464N17**
Registration date: **2020-07-20, 1399/04/30**
Registration timing: **retrospective**
Last update: **2020-07-20, 1399/04/30**
Update count: **0**

Registration date
2020-07-20, 1399/04/30

Registrant information

Name
Shamsolmolok Najafi

Name of organization / entity
Faculty od Dentistry, Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-01-21, 1397/11/01

Expected recruitment end date
2019-03-06, 1397/12/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of the effect of laser acupuncture and transcutaneous electrical nerve stimulation on pain reduction patients with myofascial pain dysfunction syndrome

Public title

The effect of laser acupuncture and transcutaneous electrical nerve stimulation on pain reduction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Participant between 18-60 years old Patients With temporomandibular joint Disorder (TMJ) and pain equal or more than 4 according to visual analogue scale (VAS)

Exclusion criteria:

Systemic joint muscle disorder Treated With Another Treatment Pregnancy History of Trauma to face

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

By table of random numbers

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, next to atomic energy institution, North Amirabad Avenue

City

Tehran

Province

Tehran

Postal code

1477935457

Approval date

2017-11-05, 1396/08/14

Ethics committee reference number

IR.TUMS.DENTISTRY.REC.1396.3872

Health conditions studied

1

Description of health condition studied

Tempolar-Mandibular joint Disorder

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Tempolar mandibolar joint Pain

Timepoint

Measuring the pain at the beginning of the study (before the intervention) and twice a week for 5 weeks (totally ten sessions) and one month after the last session as follow up

Method of measurement

VAS Questionary

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: acupuncture group, Laser acupuncture is a method based on stimulating traditional acupuncture points with low power laser, in this group 11 patient were treated with diode laser with 940 nm (Epic, Biolase, USA) and 0.5 w for 40 seconds with continuous mode, tip diameter 5mm and cross section 0.19 cm2 in 3 acupuncture points of LI4, ST6, ST7 in each side.

Category

Treatment - Devices

2

Description

control group: Physiotherapy group with TENS for transcutaneous electrical nerve stimulation that 11 patients were treated with TENS (710 L) (Iran novin) device during 10 sessions for 20 min and 180 Hz frequently and Width 300 micro second.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Tehran University of Medical Sciences

Full name of responsible person

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Sponsors / Funding sources

1

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

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available