

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative evaluation of Low level laser therapy and Trans Epidermal Nerve stimulation as adjuvant therapies to drug therapy in Myofascial pain dysfunction syndrome

Protocol summary

Summary

Objectives: Determination the amount of pain changes with low level laser therapy and trans epidermal nerve stimulation in patients with myofascial pain dysfunction syndrome. Design: This study is a Randomized clinical trial. The study population is referred patients with myofascial pain dysfunction syndrome to the department of oral and maxillofacial medicine, Dental faculty, Tehran university of medical sciences that are divided into three groups including Laser therapy, Trans epidermal nerve stimulation and Drug therapy only, via block randomization. Setting and conduct: 10 sessions of Laser therapy twice a week, 10 sessions of TENS three times a week, drug therapy for 2 months. All the groups will receive the drugs. Participants: Inclusion criteria: Pain and tenderness of masticatory muscles. Exclusion criteria: Temporomandibular joint disorders with articular origin according to Research and Diagnostic Criteria for Temporomandibular Joint Disorders (RDC/TMD); Osteoarthritis or hernia of the disc of neck vertebra; History of trauma; Removable prosthesis or missing of more than one tooth in each quadrant; Major malocclusion (anterior openbite, maxillary unilateral lingual crossbite, overjet > 6mm). Interventions: drug therapy in control and intervention groups, low level laser therapy in one intervention group, trans epidermal nerve stimulation (TENS) in the other intervention group. Main outcome measures: primary outcome measure is pain reduction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411113144N4**
Registration date: **2015-09-05, 1394/06/14**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-05, 1394/06/14

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative evaluation of Low level laser therapy and Trans Epidermal Nerve stimulation as adjuvant therapies to drug therapy in Myofascial pain dysfunction syndrome

Public title

The effect of Laser and Trans Epidermal Nerve Stimulation on Myofascial Pain Dysfunction Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 18-60 years; Pain and tenderness of masticatory muscles with or without limitation of range of motion, click in tempromandibular joint, deviation and deflection of mandible in opening; normal posterior occlusion; Orofacial pain existing at least for 6 months. Exclusion criteria: Tempromandibular joint disorders with articular origin according to RDC/TMD criteria; Systemic diseases including cardiovascular, infectious, inflammatory ,psychological diseases , seizures and tumors which can have effect on clinical appearance of the disease; Osteoartherities or hernia of the disc of neck vertebra; History of trauma; Removable prosthesis or missing of more than one tooth in each quadrant; Major malocclusion (anterior openbite, maxillary unilateral lingual crossbite, overjet > 6mm).

Age

From **32 years** old to **74 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Block Randomization is used in this study.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Science

Street address

Vice chancellor for research of Tehran University of Medical Sciences, number 23, Dameshcue street, Palestin street, Keshavarz Blvd

City

Tehran

Postal code

Approval date

2015-03-14, 1393/12/23

Ethics committee reference number

142107

Health conditions studied

1

Description of health condition studied

Myofascial pain dysfunction syndrome

ICD-10 code

M60, M61,

ICD-10 code description

Disorders of muscles

Primary outcomes

1

Description

pain

Timepoint

before treatment, after each treatment session, after the end of treatment weekly up to 2 months

Method of measurement

visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Tablet Fluoxetine 10 mg(Tehran Daroo), once a day Tablet Clonazepam 0.25 mg(Sobhan Daroo), once a day Tablet Baclofen(Zahravi) 10 mg, three times a day

Category

Treatment - Drugs

2

Description

low level laser therapy(Ga-Al-Arsen,countinus wave, $\lambda=660$ nm, $p=200$ mW, $t=10$ s)10 sessions, 2 times a week

Category

Rehabilitation

3

Description

Trans epidermal nerve stimulation (TENS) (NEWTENS 900F, Novin medical Engineering, P= 20w, Voltage=220v, Freq=50Hz) 10 session, 3 times a week

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of oral and maxillofacial medicine, Dental faculty of Tehran university of medical sciences

Full name of responsible person

Maryam Sadat Sadrzadeh Afshar

Street address

Department of Oral and Maxillofacial Medicine, Ground floor, Dental faculty, Tehran University of medical sciences, North Karegar street, beside Nuclear Energy Organization

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Tehran University of Medical Sciences

Full name of responsible person

Mohammad sadegh Akhoondi

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Research Center of Dental sciences, NO 20, Ghods street, Enghelab street.

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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

Vice chancellor for research of Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Dental faculty, Tehran University of Medical Sciences

Full name of responsible person

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Position

post graduate student of oral and maxillofacial medicine

Other areas of specialty/work

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Oral and maxillofacial medicine Board

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty