Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparative Effectiveness of Transcutaneous Electrical Nerve Stimulation, Low Level Laser Therapy and Occlusal Splint in the Treatment of Muscular TMJ Disorders

Protocol summary

Study aim

Determining and comparing the effectiveness of three conservative treatment types on the TMJ patients in 1399 that have referred to the Prosthodontic Department of Shahid Beheshti University.

Design

Clinical trial including control group, with parallel, no blind, cross-over groups on 30 patients. For random selection, random.org has been used.

Settings and conduct

The interventions have been done in the Prosthodontics Department of Shahid Beheshti Dental school University by using occlusal splint, Diode laser, and TENS machine

Participants/Inclusion and exclusion criteria

Requirements for the participants: Entry criteria: Patient’s age must be between 20 to 60 years old Chronic orofacial pain (more than three months) with or without limitation of mouth opening, TMJ sound or TMJ locking. Diagnosis of Temporomandibular Disorder (pain-related or intra-articular disorders) based on the RDC/TMD diagnosis tools. Exit criteria: Recent mandibular fracture Recent facial trauma history Congenital/developmental jaw disorders Treatment history for TMD in the past month Systemic muscular-joint disease Fibromyalgia Current or past cancer history Skin disorders at the TENS and laser therapy sites Pregnancy Radiotherapy and chemotherapy treatment history Mental disorders Dental diseases Wearing partial or complete prosthesis

Intervention groups

In this study patients with temporomandibular disorders with myofascial pain put in three intervention groups: Occlusal Splint Therapy, Laser Therapy and TENS therapy. Standard treatment guideline for these patients is occlusal splint therapy, therefore in this study occlusal splint group has been considered as the control group.

Main outcome variables

Pain level Maximum mouth opening Right lateral mandible movement Left lateral mandible movement Protrusion Eating hard food pain Eating soft food pain Speaking pain Laughing pain Yawning pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211020052823N1**
Registration date: **2021-12-22, 1400/10/01**
Registration timing: **registered_while_recruiting**

Last update: **2021-12-22, 1400/10/01**
Update count: **0**

Registration date

2021-12-22, 1400/10/01

Registrant information

Name

Nazieh Abdollah Kookhi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

nazikookhi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-11, 1400/08/20

Expected recruitment end date

2022-01-10, 1400/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Effectiveness of Transcutaneous Electrical Nerve Stimulation, Low Level Laser Therapy and Occlusal Splint in the Treatment of Muscular TMJ Disorders

Public title

Comparative Effectiveness of Transcutaneous Electrical Nerve Stimulation, Low Level Laser Therapy and Occlusal Splint in the Treatment of Muscular TMJ Disorders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1. Patient’s age between 20 to 60 years old 2- Chronic Myofascial Pain Disorder for more than 3 months 3- Diagnosis of Temporomandibular Disorder (base on RDC/TMD)

Exclusion criteria:

Recent fracture of mandible bone History of recent trauma to the face Congenital disorder of jaws History of treatment for TMD in the past month Systemic disease of muscle Fibromyalgia History of Cancer Cutaneous lesion in the site that apply laser and tens Pregnancy History of Chemotherapy and Radiotherapy Psychological Disorder Dental and Oral Disease Wearing denture and Partial denture

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients assign to 3 treatment groups through randomized block design. Subjects will be divided into 5 blocks of 6 patients for a total of 30 patients. In each block patients are randomly assigned to a specific treatment in Excel. So, in this randomized block design patients will receive random treatment based on their arrival.

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 Shahid Beheshti University of Medical Sciences

Street address

Department of Prosthodontics, School of Dentistry, Shahid Beheshti University of Medical Science, Daneshjou Blvd, Velenjak St, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983969411

Approval date

2020-09-08, 1399/06/18

Ethics committee reference number

IR.SBMU.DRC.REC.1399.028

Health conditions studied

1

Description of health condition studied

Temporomandibular Joint (TMJ) Disorders

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The effect of treatment on Muscular Pain Level

Timepoint

Measuring the Muscular Pain Level at the beginning of the trail, just after treatment, one month, and 3 months after treatment

Method of measurement

Visual Analog Scale

Secondary outcomes

1

Description

Maximum Mouth Opening

Timepoint

Before intervention, just after treatment, 1 month and 3 months after treatment

Method of measurement

Millimeter

2

Description
Right Lateral Movement of Mandible
Timepoint
Before intervention, just after, 1 month and 3 month after treatment
Method of measurement
Millimeters

3

Description
Left Lateral Movement of Mandible
Timepoint
Before intervention, just after, 1 month and 3 months after treatment
Method of measurement
Millimeter

4

Description
Protrusion
Timepoint
Before intervention, just after, 1 month and 3 months after treatment
Method of measurement
Millimeter

5

Description
Pain during eating hard food
Timepoint
Before intervention, just after, 1 month and 3 months after treatment
Method of measurement
Visual Analog Scale

6

Description
Pain during eating soft food
Timepoint
Before intervention, just after, 1 month and 3 months after treatment
Method of measurement
Visual Analog Scale

7

Description
Pain during speaking
Timepoint
Before intervention, just after, 1 month and 3 months after treatment
Method of measurement
Visual Analog Scale

8

Description
Pain during laughing
Timepoint
Before intervention, just after, 1 month and 3 months after treatment
Method of measurement
Visual Analog Scale

9

Description
Pain during yawning
Timepoint
Before intervention, just after, 1 month and 3 months after treatment
Method of measurement
Visual Analog Scale

Intervention groups

1

Description
Control group: Occlusal Splint Group (using for 3 months over night)
Category
Treatment - Devices

2

Description
Intervention group: Low Level Laser Therapy- 8 sessions- on the 18 spots on Temporalis and Masseter Muscle bilaterally
Category
Treatment - Devices

3

Description
Intervention group: Transcutaneous Electrical Nerve Stimulation (TENS)- 8 sessions- apply on Temporalis and Masseter muscles. time: 20 min- frequency: 180 Hz- width: 45 us.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Prosthodontics, School of Dentistry, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Nazieh Abdollah Kookhi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Research and Technology of Shahid Beheshti University of Medical Sciences

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Majid Sedaghat Monfared

Position
Assistant Professor of Prosthodontics

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Position
Assistant Professor of Prosthodontics

Latest degree
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Person responsible for updating data

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Postgraduate Student of Prosthodontics

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Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All patient's data including: Age, gender, treatment groups and treatment result are shareable.

When the data will become available and for how long

Simultaneous with published result

To whom data/document is available

Researchers of Academic Institutions

Under which criteria data/document could be used

Quantitative Analysis

From where data/document is obtainable

Nazieh Andollah Kookhi 00989183746219
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What processes are involved for a request to access data/document

Approximately one month after receiving email

Comments