

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Role of transcutaneous electrical nerve stimulation in temporomandibular joint disorders: a randomized controlled trial

Protocol summary

Study aim

The aim of this study was to compare the efficacy of Transcutaneous Electrical Nerve Stimulation (TENS) with commercially available analgesics in alleviating symptoms of TMDs

Design

It was a randomized, factorial group, non blinded, single center study including 140 patients in total.

Settings and conduct

A randomized controlled trial was conducted from March 11, 2020 to December 30, 2022 in Oral & Maxillofacial Surgery Department at Armed Forces Institute of Dentistry, Rawalpindi, Pakistan

Participants/Inclusion and exclusion criteria

Participants who met specific inclusion criteria were included in the investigation. Individuals between ages of 18 and 65 who had been diagnosed with Temporomandibular Joint Dysfunction (TMD) and were experiencing pain or distress in the temporomandibular joint region met these criteria. To assure the safety and validity of the study results, certain exclusion criteria were established. Excluded from the study were patients with contraindications for TENS or analgesic use, such as pacemakers, epilepsy, or pregnancy. In addition, participants who had previously received TENS or analgesic treatment for TMD were excluded. Patients with severe medical conditions that could not tolerate treatment were also excluded.

Intervention groups

The study included a total of 140 TMD patients that were randomly assigned to three groups: TENS (n=50), analgesic (n=50), and control group (n=40).

Main outcome variables

Pain intensity was assessed using the Visual Analog Scale (VAS).

General information

Reason for update

There was incorrect study design mentioned in study protocol summary.

Acronym

IRCT registration information

IRCT registration number: **IRCT20230622058557N1**

Registration date: **2023-06-27, 1402/04/06**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-04, 1402/04/13**

Update count: **1**

Registration date

2023-06-27, 1402/04/06

Registrant information

Name

Syeda Mahnoor Fatima

Name of organization / entity

National University of Medical Sciences

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Pakistan

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-01, 1399/10/12

Expected recruitment end date

2023-07-15, 1402/04/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Role of transcutaneous electrical nerve stimulation in temporomandibular joint disorders: a randomized controlled trial

Public title

TENS in temporomandibular joint dysfunction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Participants who met specific inclusion criteria were included in the investigation. Individuals between ages of 18 and 65 who had been diagnosed with Temporomandibular Joint Dysfunction (TMD) and were experiencing pain or distress in the temporomandibular joint region met these criteria. Dysfunction of masticatory muscles Restrictive jaw movements at Temporomandibular Joint Clicking sound at Temporomandibular Joint Sensitivity to palpation at Temporomandibular Joint

Exclusion criteria:

patients with contraindications for TENS or analgesic use, such as pacemakers, epilepsy, or pregnancy participants who had previously received TENS or analgesic treatment for TMD were excluded severe medical conditions

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was performed using a sealed envelope with a computer-generated random allocation for each patient. According to the this, patients were randomly divided to receive either be in the TENS Group, Analgesics Group or Control Group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ETHICS COMMITTEE Armed Forces Institute of Dentistry (AFID)

Street address

Armed Forces Institute of Dentistry, CMH, Rawalpindi

City

Rawalpindi

Postal code

46000

Approval date

2020-03-09, 1398/12/19

Ethics committee reference number

Ref:905/Trg-ABP1K2

Health conditions studied

1

Description of health condition studied

Temporomandibular joint disorder: a group of conditions that cause pain and dysfunction in the jaw joint and muscles that control jaw movement.

ICD-10 code

M26.6

ICD-10 code description

Temporomandibular joint disorders

Primary outcomes

1

Description

Decrease in Pain as shown by Decrease in VAS Pain Ratings

Timepoint

1,2,3,4 Weeks after intervention

Method of measurement

Visual Analogue Score (VAS)

Secondary outcomes

1

Description

Functional Impairment- Relief in mouth opening

Timepoint

2,3,4 Weeks after intervention

Method of measurement

MMO- Millimeter mouth opening

Intervention groups

1

Description

Intervention group: TENS group. ATENS machine is a small, battery-operated device that has leads connected to sticky pads called electrodes which were placed in close proximity to the temporomandibular joint and it sends low voltage electrical currents stimulating the nerves. TENS parameters, including frequency, pulse

duration, and intensity, were established in accordance with established TMD treatment guidelines.

Category

Treatment - Devices

2

Description

Intervention group: Analgesic Group. The analgesic group was administered commercially available analgesics for the treatment of TMD discomforts i.e. Naproxen (500mg twice daily) and muscle relaxant, Diclofenac Potassium (50mg twice daily).

Category

Treatment - Drugs

3

Description

Control group: The control group received no intervention but generalized counselling to decrease stress and heat therapy to relief pain.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Armed Forces Institute of Dentistry/ National University of Medical Sciences

Full name of responsible person

Syeda Mahnoor Fatima

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Sponsors / Funding sources

1

Sponsor

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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

Armed Forces Institute of Dentistry

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Other

Person responsible for general inquiries

Contact

Name of organization / entity

Armed Forces Institute of Dentistry affiliated with National University of Medical Sciences

Full name of responsible person

Syeda Mahnoor Fatima

Position

Senior Registrar

Latest degree

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Other areas of specialty/work

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Email

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

It is the organization's policy to not share IPD.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

Title and more details about the data/document

The data is entered in SPSS Software.

When the data will become available and for how long

6 months after publication for a period of 3 months.

To whom data/document is available

To Medical and Dental Academic Institutes.

Under which criteria data/document could be used

Academic professionals studying in Medical & Dental Institutes.

From where data/document is obtainable

Email to investigator

What processes are involved for a request to access data/document

Email to investigator

Comments