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 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

Medical doctor

Other areas of specialty/work

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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