Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of Pharmacologic treatment and Physical therapy on Myofascial Pain Disorders

Protocol summary

Study aim
Comparison of the effect of Pharmacologic therapy and Physical therapy on Myofascial Pain and Dysfunction

Design
The clinical trial has a control group, single-blind, with parallel groups, randomized, phase 3 on 30 patients. The card shuffle method was used for randomization.

Settings and conduct
The study is single blind and patients are blind.The first group is treated with Transcutaneous Electrical Nerve Stimulation(TENS) device.They should also use placebo medicine, which is similar in taste, color, and packaging to the original drugs.The second group is treated with the 500mg Naproxen and 2mg Diazepam and the TENS device off. How to prescribe the medicines to all patients, each drug is twice a day for 10 days. Also, all patients see a physiotherapist once a week for 4 weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria include patients with Myofascial Pain and Dysfunction, the chief complaint of acute pain (less than 6 months) on at least one side with/without mouth opening and exclusion criteria include other types of Temporomandibular Disorders, Systemic joint diseases (Such as rheumatoid arthritis), A history of recent trauma, Complete or partial edentulousness, Pregnancy, Breastfeeding, Patients undergoing orthodontic treatment, Patients who are unable to use medications due to systemic problems, and patients who are receiving treatment Other used.

Intervention groups
The first group is treated with Transcutaneous Electrical Nerve Stimulation device and must use placebo medicine. The second group is treated with the 500mg Naproxen and 2mg Diazepam and the Transcutaneous Electrical Nerve Stimulation device off. How to prescribe medicine to all patients, each drug is twice a day for10 days. Also, all patients see a physiotherapist once a week for 4 weeks.

Main outcome variables
Pain rate, Maximum Mouth Opening without Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210505051187N1**
Registration date: **2021-06-02, 1400/03/12**
Registration timing: **prospective**

Last update: **2021-06-02, 1400/03/12**
Update count: **0**

Registration date
2021-06-02, 1400/03/12

Registrant information

Name
sahere soltani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 58 3222 2361

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sahere.soltani@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-05, 1400/03/15

Expected recruitment end date
2021-07-21, 1400/04/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effect of Pharmacologic treatment and Physical therapy on Myofascial Pain Disorders

Public title
Comparison of the effect of Pharmacologic treatment and Physical therapy on Myofascial Pain Disorders

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with Myofascial Pain Disorders The chief complaint of acute pain (less than 6 months) on at least one side with / without restriction in opening the mouth

Exclusion criteria:
Other types of Temporomandibular Disorders Systemic joint diseases (such as Rheumatoid arthritis) A recent history of trauma Complete or partial edentulousness Pregnancy Breastfeeding Patients undergoing orthodontic treatment Patients who are unable to use the desired drugs due to systemic problems Patients who used other treatments

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to randomize, simple randomization will be used by shuffling the card. In this way, the number 1 is assigned to the first group and the number 2 assigned to the second group. The number 1 is written on 15 cards and the number 2 is written on 15 cards, then the cards are merged (shuffled) and one card is removed and The allocation is recorded and then the card is returned to the card collection.

Blinding (investigator's opinion)
Single blinded

Blinding description
Patients are assigned to the first or second group according to randomization, but do not know the main treatment.

Placebo
Used

Assignment
Parallel

Other design features
The study has two groups, the first group is treated with Transcutaneous Electrical Nerve Stimulation and Placebo medicine and the second group is treated with medicine and transcutaneous electrical nerve stimulation is given as a placebo (ie the device is turned off).

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of North Khorasan University of Medical Sciences

Street address
Al-zahra Student Dormitory, Block 1, Alley 6, Shariyar St., Al-Ghadir Complex

City
Bojnurd

Province
North Khorasan

Postal code
9415837413

Approval date
2021-05-02, 1400/02/12

Ethics committee reference number
IR.NKUMS.REC.1400.013

Health conditions studied

1

Description of health condition studied
myofascial pain disorders

ICD-10 code
M26.69

ICD-10 code description
Other specified disorders of temporomandibular joint

Primary outcomes

1

Description
Pain

Timepoint
At the beginning of the intervention and 10 days after the beginning of the intervention and at the end of the intervention

Method of measurement
The visual Analogue Scale is used to record the amount of pain, which is zero without pain and 10 is the highest amount of pain imaginable for the patient. At each assessment session, the patient should mark their pain on a visual analogue scale.

2

Description
Maximum mouth opening without pain

Timepoint
At the beginning of the intervention and 10 days after the beginning of the intervention and at the end of the intervention

Method of measurement
Distance between incisal edge of maxillary and mandibular incisors at Maximum mouth opening without pain

Secondary outcomes

empty

Intervention groups

1

Description
First intervention group: This group is treated with Transcutaneous Electrical Nerve Stimulation device (manufactured by Novin Company) with high frequency and pulse width of 25 mA. The device is set to 100 Hz while the stimulus intensity is adjusted depending on the patient's tolerance. Stimulation is given to the patient while sitting. Surface electrodes are placed in the sigmoid notch and behind the neck to complete the circuit. Gently wipe the pad location with an isopropyl alcohol to remove skin oils or substances that may interfere with the flow. In men, facial hair should be shaved. Then the pads are inserted and the connection is established. The physiotherapist must adjust the settings according to the patient's sensation. Patients visit a physiotherapist once a week for 4 weeks for treatment with the device. Each treatment session with this method lasts 30 minutes. Prolonged treatment should be avoided, as this device creates a vague pain, which gradually increases in severity, and all operations are performed by a physiotherapist. The first group is also given a placebo medicine. The method of preparation of placebo medicine for similarity in packaging, taste and appearance is that starch is poured into capsules 500 mg (for similarity with naproxen) and 10 mg (for similarity with diazepam). The medicine are prescribed in such a way that both drugs are used twice a day for 10 days.
Category
Treatment - Devices

2

Description
second Intervention group: This group is treated with the medicine and the capsule of 500 mg Naproxen and the capsule of 2 mg Diazepam are each given twice daily for 10 days. In this group, in order to be similar in terms of packaging, taste and appearance of placebo medicine with the main medicine, 500 mg Naproxen tablet is powdered and poured in the same type of 500 mg capsule and also 2 mg Diazepam is powdered and poured in the same type of 10 mg capsule. In group 2, all treatments with Transcutaneous Electrical Nerve Stimulation are similar to the first intervention group, except that the device is off.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of the School of Dentistry, North Khorasan University of Medical Sciences
Full name of responsible person
Sahere Soltani
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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?
No
Title of funding source
Bojnourd 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
Bojnourd University of Medical Sciences
Full name of responsible person
Sahere Soltani
Position
Assistant professor
Latest degree
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Person responsible for updating data

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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