Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Aug 2026

A comparative study of the effect of two methods of transcutaneous supraorbital nerve stimulation and transcutaneous infraorbital nerve stimulation in improving clinical symptoms and preventing a new attack in patients with migraine

Protocol summary

Study aim
Determine of the effect of two methods of transcutaneous supraorbital nerve stimulation and transcutaneous infraorbital nerve stimulation in improving clinical symptoms in patients with migraine

Design
The clinical trial, with parallel groups, single-blind, randomized on 81 patients

Settings and conduct
In this randomized single-blind clinical trial study, 81 patients with migraine referred to the neurology clinic of Al-Zahra Hospital in Isfahan will be included in the study and randomly divided into three groups. One group will be under nerve stimulation in the super-orbital region, one group will be under nerve stimulation in the infraorbital region and the other group will be without nerve stimulation. Patients with migraine severity will then be evaluated and compared between the three groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria include patients with migraine, in the age group above 18 and under 65 years. Exclusion criteria include use of migraine prevention in the last two weeks, use of migraine prevention methods such as nerve block, Botox injection, etc. in the previous year, headache due to overdose medication, having severe psychiatric illnesses or physical disorders, having other types of headaches (such as tension and clustering), pregnancy and lactation, opioid use and failure to complete treatment sessions.

Intervention groups
Intervention group 1: For patients, TENS therapy is performed through the electrode pads for the TENS device in the bilateral supraorbital area. Intervention group 2: For patients, TENS therapy is performed through the electrode pads for the TENS device in the bilateral infraorbital area. Control group: Sham-TENS electrodes are installed in the supraorbital area that does not conduct current.

Main outcome variables
Migraine severity, Disability score in a person's life, Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N37**
Registration date: **2021-08-14, 1400/05/23**
Registration timing: **prospective**

Last update: **2021-08-14, 1400/05/23**
Update count: **0**

Registration date
2021-08-14, 1400/05/23

Registrant information

Name
Asieh Maghami Mehr

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-22, 1400/05/31

Expected recruitment end date
2021-10-23, 1400/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study of the effect of two methods of transcutaneous supraorbital nerve stimulation and transcutaneous infraorbital nerve stimulation in improving clinical symptoms and preventing a new attack in patients with migraine

Public title
The effect of two methods of transcutaneous supraorbital nerve stimulation and transcutaneous infraorbital nerve stimulation in improving clinical symptoms in patients with migraine
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age category above 18 and under 65 years Patients with migraine
Exclusion criteria:
Use of migraine prevention in the last two weeks Use of migraine prevention methods such as nerve block, Botox injection, etc. in the previous year Headache due to overdose medication Having severe psychiatric illnesses or physical disorders Having other types of headaches (such as tension and clustering) Pregnancy and lactation Opioid use Failure to complete treatment sessions
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **81**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 81 eligible patients will be randomly selected. Then random numbers are created by computer software "Random Allocation". We randomly divide these numbers into three parts. Each number is written on paper and placed in an envelope. Then each patient is asked to choose an envelope from among the envelopes. According to the selected envelope, the patient will be assigned to one of the three groups.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the difference in the area under nerve stimulation, the intervener is aware of the type of intervention. However, the patient and the person recording the patient's clinical information and the statistical analyst will not be aware of the type of intervention.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq
City
Isfahan
Province
Isfehan
Postal code
8179964167
Approval date
2021-02-07, 1399/11/19
Ethics committee reference number
IR.MUI.MED.REC.1399.1024

Health conditions studied

1

Description of health condition studied
Migraine
ICD-10 code
G43.909
ICD-10 code description
Migraine, unspecified, not intractable, without status migrainosus

Primary outcomes

1

Description
Migraine severity
Timepoint
Before the intervention and three months after the intervention
Method of measurement
Questionnare of Headache Impact Test 6 score (HIT-6)

2

Description
Disability score in a person's life
Timepoint
Before the intervention, 1 and 3 months after the intervention
Method of measurement
Migrain disability assessment test (MIDAS)

3

Description
Pain
Timepoint
Before the intervention, 1 and 3 months after the intervention
Method of measurement
Visual Analog Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group 1: For patients, TENS therapy is performed through the electrode pads for the TENS device in the bilateral supraorbital area (intensity: 10 mA, which of course can be reduced depending on individual tolerance - frequency 100 for 30 minutes) for six sessions per week for 4 weeks
Category
Treatment - Other

2

Description
Intervention group 2: For patients, TENS therapy is performed through the electrode pads for the TENS device in the bilateral infraorbital area (intensity: 10 mA, which of course can be reduced depending on individual tolerance - frequency 100 for 30 minutes) for six sessions per week for four weeks
Category
Treatment - Other

3

Description
Control group: Sham-TENS electrodes are installed in the supraorbital area that does not conduct current.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Saeid Khosrawi
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Department of Physical Medicine and Rehabilitation, Al-Zahra Hospital, Sofeh Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Isfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Saeid Khosrawi
Position
Professor
Latest degree
Subspecialist
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
There is no further information
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