Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Effects of non-invasive vagus nerve stimulation and vestibular rehabilitation on dizziness, and postural control in adults with vestibular migraine

Protocol summary

Study aim
Effects of non-invasive vagus nerve stimulation and vestibular rehabilitation on dizziness, and postural control in adults with vestibular migraine

Design
Randomized, clinical trial with a parallel group design on 28 patients. Randomization was carried out with Random Allocation Software.

Settings and conduct
Setting: School of Rehabilitation, TUMS. Recruitment of patients with vestibular migraine based on inclusion criteria, random allocation, intervention based on the group description (VR/nVNS/VR+nVNS/VR+shamnVNS) for 4 weeks, and assessment and comparison of balance system (DHI, VSS, vHIT, and static postural control) outcomes before and after interventions.

Participants/Inclusion and exclusion criteria
Patients diagnosed with Vestibular Migraine (diagnosed by a neurologist and based on ICDH-3 guidelines)

Intervention groups
1)VR group: receiving vestibular rehabilitation every day for four weeks 2) nVNS group: receiving nVNS (12 sessions, three times a week for 4 weeks, each stimulation session for 30 minutes) 3) VR+nVNS group: receiving vestibular rehabilitation and nVNS 4) VR+ShamnVNS group: received vestibular rehabilitation and sham nVNS

Main outcome variables
The overall score and subcategories of the Dizziness Handicap Inventory Questionnaire, the overall score of the vertigo Symptoms Scale Questionnaire (short version), the frequency of vertigo/dizziness, video head Impulse Test, static posturography.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160131026279N5**
Registration date: **2023-06-25, 1402/04/04**
Registration timing: **registered_while_recruiting**

Last update: **2023-06-25, 1402/04/04**
Update count: **0**

Registration date
2023-06-25, 1402/04/04

Registrant information
Name
Mansoureh Adel Ghahraman
Name of organization / entity
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Iran (Islamic Republic of)
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+98 21 7753 4364
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-06-21, 1402/03/31

Expected recruitment end date
2026-01-19, 1404/10/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effects of non-invasive vagus nerve stimulation and

vestibular rehabilitation on dizziness, and postural control in adults with vestibular migraine

Public title
The effect of rehabilitation and non-invasive vagus nerve stimulation on the treatment of vestibular migraine

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age range of 18-50 years, people with vestibular migraine (diagnosed by a neurologist and based on ICDH-3 guidelines) no change in preventive medications during the last 2 months and during the study, no use of suppressive medications Compensating the vestibular system with the opinion of an expert doctor related to the thesis, no history of other vestibular disorders, Meniere's disease, ear surgery, intracranial surgery, posterior circulation stroke, epilepsy, severe cardiovascular disease, severe carotid artery disease, Previous carotid artery surgery, or implanted electrical devices. no visual and motor deficit, no history of previous vestibular rehabilitation program, sufficient visual acuity to see the target point in the vHIT test.

Exclusion criteria:
Use of drugs that suppress vestibular system compensation, suffering from neck pain and limited range of motion of the neck, alcohol and drug use, history of orthopedic problems in the last 6 months obvious deformity of the lower limbs such as scoliosis and kyphosis based on the observation of a physiotherapist history of rheumatic or metabolic diseases based on individual report.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **28**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Individual random assignment to four equal groups with block randomization method using blocks of size 4; Randomization and random sequential allocation: done with Random Allocation Software;

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 School of Nursing and Midwifery & Rehabilitation - Tehran University of Medical

Street address
Enghelab Ave.

City
Tehran

Province
Tehran

Postal code
1148956111

Approval date
2023-02-01, 1401/11/12

Ethics committee reference number
IR.TUMS.FNM.REC.1401.160

Health conditions studied

1

Description of health condition studied
vestibular migraine

ICD-10 code
G43

ICD-10 code description
Migraine

Primary outcomes

1

Description
Dizziness Handicap Inventory score

Timepoint
Before and after intervention

Method of measurement
Dizziness Handicap Inventory

2

Description
The total score of the vertigo symptom scale

Timepoint
Before and after intervention

Method of measurement
the vertigo symptom scale

3

Description
Frequency of vertigo/dizziness

Timepoint
Before and after intervention

Method of measurement
vertigo/Dizziness frequency form with numbering 0-6

4

Description
Vestibulo-ocular reflex gain
Timepoint
Before and after intervention
Method of measurement
video head impulse test (vHIT)

5

Description
Frequencyof covert and overt saccades
Timepoint
Before and after intervention
Method of measurement
video head impulse test (vHIT)

6

Description
Displacement of center of pressure in both anterior-posterior and medial-lateral directions
Timepoint
Before and after intervention
Method of measurement
Static posturography on force-plate and calculation with formula

7

Description
velocity of displacement of center of pressure in both anterior-posterior and medial-lateral directions
Timepoint
Before and after intervention
Method of measurement
Static posturography on force-plate and calculation with formula

8

Description
Overall average velocity
Timepoint
Before and after intervention
Method of measurement
Static posturography on force-plate and calculation with formula

9

Description
The area of displacement of the center of pressure
Timepoint
Before and after intervention
Method of measurement
Static posturography on force-plate and calculation with formula

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group 1 (VR): receiving vestibular rehabilitation program (exercises including seven VOR exercises, eight static VSR exercises and five dynamic VSR exercises), every day, 4 weeks.
Category
Rehabilitation

2

Description
Intervention group: Intervention group 2 (nVNS): receiving non-invasive vagus nerve stimulation, each stimulation session for 30 minutes (frequency 1 Hz, duration 0.2 milliseconds and the intensity of stimulation is the strongest sensation that patients can tolerate without pain), three times a week, 12 sessions, 4 weeks
Category
Rehabilitation

3

Description
Intervention group: Intervention group 3 (VR+nVNS): receiving vestibular rehabilitation exercises along with non-invasive vagus nerve stimulation, 4 weeks
Category
Rehabilitation

4

Description
Intervention group: Intervention group 4 (VR+sham nVNS): receiving vestibular rehabilitation exercises along with non-invasive vagus nerve stimulation as a sham, 4 weeks
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
The Neurology Clinic of Sina Hospital, Tehran, and Audiology clinic, School of Rehabilitation, Tehra
Full name of responsible person
Mansoureh Adel Ghahraman
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Hamid Dalvand
Street address
School of Rehabilitation, Pich-e-hemiran, Enghelab Ave.
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rehabilitation@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Mansoureh Adel Ghahraman
Position
Associate Professor
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Reporting as a PhD dissertation and papers
When the data will become available and for how long
2025 and after
To whom data/document is available
All people
Under which criteria data/document could be used
Dissertation: In accordance with Tehran University of Medical Sciences copyright Paper: In accordance with the journal's policies to access the published paper
From where data/document is obtainable
Dissertation: The library of the School of Rehabilitation, TUMS Papers: Databases
What processes are involved for a request to access data/document
For the dissertation, studying in the library For papers depends on the journal's policy.
Comments