Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigating the Effect of auricular vagus nerve stimulation on Target Gait improvement in patients with Parkinson disease and freezing of Gait

Protocol summary

Study aim
Determining the effect of stimulation of the auditory branch of the vagus nerve on the improvement of movement and gait problems of parkinsonian patients with freezing

Design
controlled, parallel-group, double-blind, randomized clinical trial on 54 patients with parkinsonian freezing gait.

Settings and conduct
Parkinsonian patients with freezing of gait who were referred to the neurology department of Imam Khomeini Hospital in Tehran are eligible to enter the study, after randomization, the stimulation group will receive stimulation of the auditory branch of the vagus nerve through the skin by the patient at home. and the other group receives the sham stimulation. Motion indicators will be measured once at baseline and at the end of two weeks at the Imam Khomeini Hospital Complex in Tehran. The patients and the evaluator are blinded to the type of intervention received by the patient.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Hoehn & Yahr index between 2 and 3 2. Ability to walk 30 meters and turn 180 degrees without assistance 3. fixed dosage of medication in past two months 4. be able to follow simple verbal commands 5. younger than 76 years old. Exclusion criteria: 1. The presence of specific musculoskeletal disorders 2. cardiac disorders 3. Diabetes 4. The presence of cognitive, breath and vision problems 5. Neurological disorders other than Parkinson's 6. Body mass index above 30

Intervention groups
Stimulation of the auricular branch of the vagus (two electrodes: 1. right ear concha, 2. patient's shoulder) with a frequency of 20 Hz and electric current adjusted according to the patient's tolerance and for two weeks twice a day, for 20 minutes each time.

Main outcome variables
The movements and gait problems

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20121110011424N6**
Registration date: **2024-05-08, 1403/02/19**
Registration timing: **prospective**

Last update: **2024-05-08, 1403/02/19**
Update count: **0**

Registration date
2024-05-08, 1403/02/19

Registrant information

Name
Abbas Tafakhori

Name of organization / entity
Iranian Center of Neurological Research

Country
Iran (Islamic Republic of)

Phone
+98 21 6691 0491

Email address
a_tafakhori@sina.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-06-19, 1403/03/30

Expected recruitment end date
2025-06-20, 1404/03/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the Effect of auricular vagus nerve stimulation on Target Gait improvement in patients with Parkinson disease and freezing of Gait

Public title
Effect of auricular vagus nerve stimulation in Parkinson disease and freezing of Gait

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Hoehn & Yahr index between 2-3 able to walk 30 meters without help Has been treated with a stable dose of dopaminergic drugs in the last two months Able to follow simple verbal commands The patient can turn 180 degrees at one point The age of patients should be less than 76 years. The Montreal cognitive assessment index should be less than 21.

Exclusion criteria:
Presence of specific musculoskeletal disorders Heart problems, especially arrhythmias and having a pacemaker History of stroke and myocardial infarction Diabetes and neuropathy The presence of cognitive, vision and breathing problems that affect the performance of tasks Neurological disorders other than Parkinson's Surgery that affects the movement of patients. The patient needs assistance to walk. Body mass index above 30 A history of receiving vagus nerve stimulation Taking anticholinergic drugs or cholinesterase inhibitors Freezing of Gait for reasons other than Parkinson's

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **54**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients were divided into 2 groups with sequentially numbered method(randomization with the random number builder software).

Blinding (investigator's opinion)
Double blinded

Blinding description
1. Blinding of the patient: the patient will not know whether he will receive the stimulation or not. 2. Gait Analyzer: He will not know that the patient has received stimulation or the sham procedure. Only the investigator will know that the patient received stimulation or sham procedure.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tehran University of Medical Sciences

Street address
Qods Avenue, Tehran

City
Tehran

Province
Tehran

Postal code
1419733141

Approval date
2024-03-10, 1402/12/20

Ethics committee reference number
IR.TUMS.IKHC.REC.1403.007

Health conditions studied

1

Description of health condition studied
Parkinson's disease

ICD-10 code
G20

ICD-10 code description
Parkinson's disease

Primary outcomes

1

Description
The improvement of movements and gait problems of parkinsonian patients with freezing

Timepoint
Before intervention and 2 weeks after intervention

Method of measurement
Gate analysis with force plate and motion analyzer and MDS-UPDRS questionnaire

2

Description
Adverse effect

Timepoint
2 weeks after intervention

Method of measurement
Adverse effect form

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Stimulation of the vagal branch of the ear (location of two electrodes: 1. right ear concha, 2. patient's shoulder (in the form of a pad-like plate)) with a frequency of 20 Hz and electric current adjusted according to the patient's tolerance and for two weeks once a day Once in the morning and the next time in the evening, by patient at home for 20 minutes each time
Category
Treatment - Devices

2

Description
Control group: Sham intervention without receiving electric current (location of two electrodes: 1. right ear concha, 2. patient's shoulder (in the form of a pad-like plate)) for two weeks twice a day, once in the morning and the next time in the evening, by Self-care at home for 20 minutes each time
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospial
Full name of responsible person
Abbas Tafakhori
Street address
Imam Khomeini Hospital Complex, Keshavarz Blvd., Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Phone
+98 21 6119 0000
Email
Imamhospital@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ali Akbari Sari
Street address
Qods St., Keshavarz Blvd., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1416633591
Phone
+98 21 8163 3685
Email
vcr@sina.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
Reza Samiee
Position
Medical extern
Latest degree
Bachelor
Other areas of specialty/work
Neurology
Street address
No.1, Iranika apartment, 6th Nobakht Ave, Nobakht St
City
Gorgan
Province
Golestan
Postal code
4915659687
Phone
+98 17 3232 4159
Email
Rezasamieepgh@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Abbas Tafakhori
Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Neurology
Street address
Neurology research center, Imam Khomeini Hospital Complex, Keshavarz Blvd, Tehran
City
Tehran
Province
Tehran
Postal code
1419733141
Phone
+98 21 6119 0000
Email
Abbas.tafakhori@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Reza Samiee
Position
Medical extern
Latest degree
Bachelor
Other areas of specialty/work
Neurology
Street address
No.1, Iranika apartment, 6th Nobakht Ave, Nobakht St
City
Gorgan
Province
Golestan
Postal code
4915659687
Phone
+98 17 3232 4159
Email
Rezasamieepgh@gmail.com

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
No - There is not a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Clinical and demographic data will be available
When the data will become available and for how long
When data was published
To whom data/document is available
Public
Under which criteria data/document could be used
For scientific use only
From where data/document is obtainable
From principal investigator Email Dr. Abbas Tafakhori E-mail: a_tafakhori@sina.tums.ac.ir
What processes are involved for a request to access data/document
PI approval
Comments