Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating The effect Of Self-treatment Maneuver At Home In the Recovery of Patients With Benign Paroxysmal Positional Vertigo-A Clinical Trial Study

Protocol summary

Study aim
The Efficacy Of Self-Treatment Maneuver At Home In The Recovery Of Patients With Benign Paroxysmal Positional Vertigo

Design
A Controlled Randomized Trial. A Parallel Group Design Of 86 Patients(Phase 3). SAS Software Version 9 Was Used For Randomization.

Settings and conduct
This randomized clinical trial (RCT) study was conducted on 86 patients with complaints of vertigo, who were diagnosed with benign positional vertigo (BPPV) by history and performing maneuvers. This study will be carried out in 1402 at the otolaryngology clinic of Amir Al Momenin in Rasht. The samples will be selected from among the people who referred to this department with the initial complaint of dizziness and imbalance and stated BPPV symptoms in the history taking. The rehabilitation treatment of patients with BPPV in the second group (intervention) is done using maneuver positioning training in self-treatment maneuvers at home in BPPV patients.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients Aged Between 18 To 90 Years In Whom BPPV Was Diagnosed Using The Dix-Hallpike Maneuver And Clinical Signs And Symptoms Exclusion Criteria: Patients whose cause of vertigo is other than BPPV.

Intervention groups
In the first group (control), only the Epley maneuver is performed to treat the patients. Rehabilitation treatment in the second group (intervention) is done by using the self-treatment positioning maneuver at home. In this study, Semont's modified self-treatment maneuver will be used. The patient does this 2 times on the right side and 2 times on the left side (2 times per day for 3 days).

Main outcome variables
Indicators of Benign Paroxysmal Vertigo according to DHI Scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220608055103N2**
Registration date: **2023-09-04, 1402/06/13**
Registration timing: **prospective**

Last update: **2023-09-04, 1402/06/13**
Update count: **0**

Registration date
2023-09-04, 1402/06/13

Registrant information

Name
Shadman Nemati

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 13 3322 5242

Email address
drshadmannemati_ent@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2024-01-21, 1402/11/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating The effect Of Self-treatment Maneuver At Home In the Recovery of Patients With Benign Paroxysmal Positional Vertigo-A Clinical Trial Study

Public title

The Effect Of Self-Treatment Maneuver At Home In The Recovery Of Patients With Benign Paroxysmal Positional Vertigo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

A Diagnosis Of BPPV With Dix-Hallpike Maneuver And Clinical Signs No Previous Use Of Central Nervous System Depressants Or Stimulants In The Last 24 Hours

Exclusion criteria:

Other Causes Of Vertigo, Such As CPA Tumors, Anxiety Disorders, Confirmed Or Suspected Migraine A Disease Or Condition For Which The Self-Treatment Maneuver, Or The Epley Maneuver Was Contraindicated, Such As Degenerative Disorders Of The Cervical Or Thoracic Spine, Detachment Of The Retina, Myocardial Infarction, Or Severe Obesity Nystagmus That Indicates The Central Positional Nystagmus, Or Vestibular Migraine

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **86**

Randomization (investigator's opinion)

Randomized

Randomization description

The Permuted Block Randomization Method Is Designed To Randomize Subjects Into Two Groups. It is used with a block size of 4 and an individual randomization unit. The Participants Were Randomly Assigned To Treatment Groups In Small "Blocks" Of Four Individual Participants At A Time Using SAS Software Version 9. According To The Type Of Intervention, There Is No Possibility Of Blinding. The Samples Will Be Selected From Among The People Who Referred To This Department With The Initial Complaint Of Dizziness And Imbalance And Who Stated BPPV Symptoms In The History Taking, By The Available Sampling Method By The Otolaryngologist. Interventions By The Specialist Otorhinolaryngology Will Be Performed.

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

Research Ethics Committees of Guilan university of medical sciences

Street address

Amir Al Mo'menin Educational Remedial & Research Center, 17th Shahrivar

City

Rasht

Province

Guilan

Postal code

4139637459

Approval date

2023-04-19, 1402/01/30

Ethics committee reference number

IR.GUMS.REC.1402.003

Health conditions studied

1

Description of health condition studied

Benign Paroxysmal Positional Vertigo

ICD-10 code

H81.1

ICD-10 code description

Benign Paroxysmal Vertigo

Primary outcomes

1

Description

Indicators Of Benign Paroxysmal Positional Vertigo According to DHI Scale

Timepoint

The Evaluation Of Patients Will Be Done Before Treatment And 1 Month Post-Treatment.

Method of measurement

Dizziness Handicap Inventory Scale

Secondary outcomes

1

Description

The level of patient satisfaction with the effect and comfort of the treatment performed based on the scale (Visual Analogue Scale).

Timepoint

Before Treatment And One Month Post-Treatment

Method of measurement

Videonystagmography (VNG)

Intervention groups

1

Description

Intervention group: the rehabilitation treatment of BPPV patients in the intervention group is done by using self-treatment positioning maneuver maneuvers at home . In this research, modified semont maneuver will be used. Turn your head about 45 degrees away from the side affected by bppv. In this way, patients are advised to sit on the edge of the bed, put two pillows on both sides, and first put the hand under the affected ear, an angle of about 30 to 45 degrees is given upwards and turn the head 45 degrees away from the affected side. Lie down on the affected side quickly , while the ear is down and the eyes and chin are up. Wait for 20 seconds (or in case of dizziness until the episode of dizziness ends), then quickly returns to the sitting position. Then the patients should perform the same maneuver in reverse to the opposite side. They does this 2 times on the right side and 2 times on the left side (2 times per day for 3 days).

Category

Rehabilitation

2

Description

Control Group: In the control group, only the application maneuver is performed to treat the patients. The patient is placed from a sitting position to an open arched position. His head is turned 45 degrees to the right and remains in this position for 15 to 20 seconds. Then the head is turned to the left at an angle of 45 degrees and remains in this position for 10 to 20 seconds. Then the head is placed at a ninety degree angle so that the end part of the ear hits the ground. Then we return the patient to a sitting position. The opposite of this movement is done lying to the left.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al Mo'menin Educational Remedial & Research Center

Full name of responsible person

Shadman Nemati

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

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Amiralmomenin Hospital, 17th Shahrivar, Rasht, Gilan Province

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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

Guilan 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

Guilan University of Medical Sciences

Full name of responsible person

Shadman Nemati

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work
Ear, Nose, and Throat
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Person responsible for scientific inquiries

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Latest degree
Subspecialist
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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
Yes - There is 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
all collected deidentified IPD
When the data will become available and for how long
starting after publication
To whom data/document is available
people working in academic institutions
Under which criteria data/document could be used
The full profile and CV of the applicants will be reviewed by Dr. Shadman Nemati.
From where data/document is obtainable
Email: drshadmannemati_ent@yahoo.com Address: Amir Al Mo'menin Educational Remedial & Research Center, 17th Shahrivar, Rasht, Gilan Province
What processes are involved for a request to access data/document
After reviewing the applicant's information, the applicant will be contacted by email.
Comments