

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Evaluation of the effects of vitamin D in patients with benign paroxysmal positional vertigo (BPPV)

Protocol summary

Study aim

Determining the effects of vitamin D in patients with benign paroxysmal positional vertigo

Design

Clinical trial with control and intervention groups, On100 patients, Randomized with a random number table, Not blinded

Settings and conduct

Patients with benign paroxysmal positional vertigo (BPPV) who refer to Baqiyatallah Hospital during the study will be included in the study if they are eligible and will be randomly assigned to two intervention and control groups using a random number table method. Blinding was not performed in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with confirmed benign paroxysmal positional vertigo, over 18 years of age, vitamin D levels between 30 and 50. Exclusion criteria: Failure to complete the informed consent form, Taking drugs that affect vitamin D metabolism, History of ear surgery, History of Meniere's disease, History of labyrinthitis or vestibular neuritis, Pregnancy or breastfeeding

Intervention groups

In the intervention group, in addition to standard BPPV treatment (Epley maneuver It is a treatment method performed by a physician and involves a series of four head and body movements from sitting to lying down, rolling to the side, and returning to a sitting position.), one 1000-unit vitamin D supplement tablet (Dana Pharma) is prescribed once daily with food until the end of the study (6 months). The dose of vitamin D used in this study is within the daily requirement and completely safe. In the control group, only the Epley therapeutic maneuver is performed, This is the approved standard treatment and it is recommended that patients not take vitamin D supplements until the end of the study.

Main outcome variables

the number of benign paroxysmal positional vertigo

(BPPV) attacks, the time interval between BPPV attacks, BPPV attack duration, severity of BPPV attacks, symptoms associated with BPPV

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250207064676N1**

Registration date: **2025-04-02, 1404/01/13**

Registration timing: **prospective**

Last update: **2025-04-02, 1404/01/13**

Update count: **0**

Registration date

2025-04-02, 1404/01/13

Registrant information

Name

Abas Rezaeezade

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-21, 1404/02/01

Expected recruitment end date

2025-07-23, 1404/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effects of vitamin D in patients with benign paroxysmal positional vertigo (BPPV)

Public title
Studying the effect of vitamin D on benign paroxysmal positional vertigo (BPPV)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with confirmed benign paroxysmal positional vertigo (BPPV) Over 18 years old Serum vitamin D levels should be between 30 and 50
Exclusion criteria:
 Failure to complete the informed consent form Taking drugs that affect vitamin D metabolism History of ear surgery History of Meniere's disease History of labyrinthitis or vestibular neuritis Pregnancy or breastfeeding

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, simple random selection method using a random number table will be used to select individuals. In this way, the researcher first determines the direction of movement in the table and then randomly places her finger on one of the numbers in the table. Then it moves in the direction indicated in the table and records all the numbers. Even numbers will receive the intervention method and odd numbers the control method.

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 Baqiyatallah University of Medical Sciences
Street address
 Baqiyatollah University , Molla Sadra Street, Tehran
City
 Tehran
Province
 Tehran
Postal code
 1435915371
Approval date
 2025-01-20, 1403/11/01
Ethics committee reference number
 IR.BMSU.BAQ.REC.1403.204

Health conditions studied

1

Description of health condition studied
benign paroxysmal positional vertigo(bppv)

ICD-10 code
H81.1

ICD-10 code description
Benign paroxysmal vertigo

Primary outcomes

1

Description
Number of attacks of benign paroxysmal positional vertigo

Timepoint
Evaluation of benign paroxysmal positional vertigo before intervention and one month, three months, and six months after intervention.

Method of measurement
Patient history in the form of a checklist and Hall-Pike maneuver (which is a diagnostic maneuver)

2

Description
Time interval between attacks of benign paroxysmal positional vertigo

Timepoint
Evaluation of benign paroxysmal positional vertigo before intervention and one month, three months, and six months after intervention.

Method of measurement
Patient history in the form of a checklist and Hall-Pike maneuver (which is a diagnostic maneuver)

3

Description
Duration of benign paroxysmal positional vertigo attack

Timepoint

Evaluation of benign paroxysmal positional vertigo before intervention and one month, three months, and six months after intervention.

Method of measurement

Patient history in the form of a checklist and Hall-Pike maneuver (which is a diagnostic maneuver)

4

Description

Severity of benign paroxysmal positional vertigo attacks

Timepoint

Evaluation of benign paroxysmal positional vertigo before intervention and one month, three months, and six months after intervention.

Method of measurement

Patient history in the form of a checklist and Hall-Pike maneuver (which is a diagnostic maneuver)

5

Description

Symptoms associated with benign paroxysmal positional vertigo

Timepoint

Evaluation of benign paroxysmal positional vertigo before intervention and one month, three months, and six months after intervention.

Method of measurement

Patient history in the form of a checklist and Hall-Pike maneuver (which is a diagnostic maneuver)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group : In the intervention group, in addition to standard BPPV treatment (Epley maneuver It is a treatment method performed by a physician and involves a series of four head and body movements from sitting to lying down, rolling to the side, and returning to a sitting position.), one 1000-unit vitamin D supplement tablet (Dana Pharma) is prescribed once daily with food until the end of the study (6 months). The dose of vitamin D used in this study is within the daily requirement and completely safe.

Category

Treatment - Drugs

2

Description

Control group: In this group, only the Epley maneuver is performed, which is the standard treatment, and vitamin D supplementation is not prescribed, and the patient is advised not to take vitamin D until the end of the study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Baqiyatullah Hospital

Full name of responsible person

Abas Rezaeezade

Street address

Baqiyatallah Hospital, Molla Sadra Street, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Mohammad Javad Behzadnia

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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

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Abas Rezaeezade

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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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