Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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

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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

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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

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Position
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Medical doctor

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Person responsible for updating data

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Position
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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