

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 4814 2376

##### Email address

arezaeezade72a91@gmail.com

##### 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

Baqiyatallah 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

##### **City**

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##### **Province**

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##### **Postal code**

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##### **Phone**

+98 21 8126 4090

##### **Email**

arezaeezade72a91@gmail.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Bagheiat-allah University of Medical Sciences

##### **Full name of responsible person**

Mohammad Javad Behzadnia

##### **Street address**

Baqiyatallah University , Molla Sadra Street, Tehran

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##### **Email**

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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**

Block332, Daneshjoo street ,Velayat city ,Babaei  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Bagheiat-allah University of Medical Sciences

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Resident

**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