

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### The effect of taking calcium and vitamin D on the rate of recurrence and severity of benign paroxysmal positional vertigo

#### Protocol summary

##### Study aim

The purpose of this study was to evaluate the effects of calcium and vitamin D on recurrence rate and severity of benign paroxysmal positional vertigo (BPPV) in Birjand city.

##### Design

This study is a clinical trial in patients with BPPV. This study is parallel, nonrandomized, without blindness, without placebo and without age limit. Phase 2-3

##### Settings and conduct

This study is a clinical trial in patients with BPPV in Birjand (Valiasr hospital). Sample size of the study is 86 people including 43 case and 43 control subjects. The duration of this study is 3 months that during of this period the control group will be treated with betahistine 8mg three times a day (for 10 days) and the case group will receive betahistine 8mg three times a day (for 10 days) and calcium 500mg daily (for 3 months) and vitamin D 50000 units per week (for 10 weeks). Success rate is measured based on VAS criteria.

##### Participants/Inclusion and exclusion criteria

All people with BPPV who were diagnosed with Hallpike test were included in the study. People with central lesions such as stroke, Parkinson's disease, history of psychiatric illness and severe impairment were excluded.

##### Intervention groups

Control group is treated with betahistine and the case group is treated with betahistine and calcium and vitamin D

##### Main outcome variables

severity of vertigo, the rate of recurrence of vertigo, duration of vertigo

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170505033824N1**

Registration date: **2019-08-02, 1398/05/11**

Registration timing: **retrospective**

Last update: **2019-08-02, 1398/05/11**

Update count: **0**

##### Registration date

2019-08-02, 1398/05/11

##### Registrant information

###### Name

Ali Mohammad Pourbagher-Shahri

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 56 3234 5167

###### Email address

ali.pourbagher@bums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-30, 1397/10/09

##### Expected recruitment end date

2019-03-19, 1397/12/28

##### Actual recruitment start date

2018-12-30, 1397/10/09

##### Actual recruitment end date

2019-03-15, 1397/12/24

##### Trial completion date

2019-06-14, 1398/03/24

##### Scientific title

The effect of taking calcium and vitamin D on the rate of recurrence and severity of benign paroxysmal positional vertigo

##### Public title

The effect of taking calcium and vitamin D on the rate of

recurrence and severity of benign paroxysmal positional vertigo

ir.bums.rec.1397.256

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Diagnosis of peripheral vestibular lesions and proper cognition according to Hallpike test

### Exclusion criteria:

Central lesions like stroke, Parkinson's disease, brain trauma according to a neurologist's diagnosis or history of psychiatric diseases or deformities that impair the balance, such as severe spinal deviation or deformity of the lower extremities Addict and alcoholic people and pregnant women, as well as those who are not willing to participate in the study

## Age

No age limit

## Gender

Both

## Phase

2-3

## Groups that have been masked

No information

## Sample size

Target sample size: 86

Actual sample size reached: 86

## Randomization (investigator's opinion)

Not randomized

## Randomization description

## 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 Birjand University of Medical Sciences

##### Street address

Birjand - Moallem Blvd

##### City

Birjand

##### Province

South Khorasan

##### Postal code

9717853577

#### Approval date

2018-12-28, 1397/10/07

#### Ethics committee reference number

## Health conditions studied

### 1

#### Description of health condition studied

Benign paroxysmal vertigo

#### ICD-10 code

H81

#### ICD-10 code description

Disorders of vestibular function

## Primary outcomes

### 1

#### Description

severity of vertigo

#### Timepoint

before intervention - after intervention (3 month)

#### Method of measurement

VAS criteria

### 2

#### Description

duration of vertigo

#### Timepoint

before intervention - after intervention (3 month)

#### Method of measurement

VAS criteria

### 3

#### Description

rate of recurrence of vertigo

#### Timepoint

before intervention - after intervention (3 month)

#### Method of measurement

VAS criteria

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: After hallpike test and after training on drug consumption patients will be treated with betahistine 8mg three times a day (for 10 days) and vitamin D 50000 unit (perl per week for 10 weeks) and calcium 500 mg daily (for 3 month)

#### Category

Treatment - Drugs

### 2

#### Description

Control group: After hallpike test and after training on drug consumption patients will be treated with betahistine 8mg three times a day (for 10 days)

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Vali-e-Asr hospital

**Full name of responsible person**

Dr Mohammad Mousavi

**Street address**

Birjand, Moallem Blvd

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3239 5000

**Email**

Mousavi.m903@bums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Dr Tooba Kazemi

**Street address**

Birjand - Moallem Blvd

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3238 1200

**Email**

drtooba.kazemi@gmail.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Birjand 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**

Birjand University of Medical Sciences

**Full name of responsible person**

Hadi Motamedi

**Position**

medical student

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurology

**Street address**

Birjand- Moallem Blvd

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3239 5000

**Email**

Hadi.motamedi92@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Mousavi

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Neuroscience

**Street address**

Birjand - Moallem Blvd

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3239 5000

**Email**

Mousavi.m903@bums.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Birjand University of Medical Sciences

**Full name of responsible person**

Ali Mohammad Pourbagher-Shahri

**Position**

Researcher

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Neurosurgery

**Street address**

Birjand - Moallem Blvd

**City**

Birjand

**Province**

South Khorasan

**Postal code**

9717853577

**Phone**

+98 56 3239 5000

**Email**

ali.pourbagher@bums.ac.ir

**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**

The entire statistical data from this study can be shared as needed based on the ethics committee's criteria

**When the data will become available and for how long**

The results of this study, after publishing the results as a paper, will be published and shared

**To whom data/document is available**

The data from this study will be available to all researchers.

**Under which criteria data/document could be used**

All academic researchers, in the form of research projects approved by the Ethics Committee, are allowed to access the data and perform the necessary analyzes on the documentation of this research

**From where data/document is obtainable**

Applicants for obtaining documentation of this study can request information by email with the corresponding author.

**What processes are involved for a request to access data/document**

Applicants for obtaining documentation of this study can request information by email with the corresponding author.

**Comments**