

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