

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison Effect of betahistine and dimenhydrinate with Epley maneuver to improve symptoms in patients with benign paroxysmal positional vertigo

Protocol summary

Summary

The purpose of this study was to evaluate the effect of betahistine and dimenhydrinate medications in BPPV after epley maneuver. In this study, 120 patients who their BPPV is prove with the history taking, physical examination and hallpike dix test, will be studied. Inclusion criteria: 1. Unknown BPPV 2. Patients who don't receive any medication. Exclusion criteria: 1. The inner ear disease 2. The inner or middle ear surgery 3. Migraine and headache during the study period. 4. Using Psycho-neurological drugs during the study 5. The involvement more than one of semi-circular canal 6. Re-Appearance of nystagmus after epley maneuver. Sampling will continue to reach 120 patients, The questionnaire Dizziness Handicap Inventory (DHI) and Berg balance scale (modified) will be filled for all patients. They will be divided into three treatment groups as double-blind randomized. Patients will receive drugs in sealed coded boxes. physician and patient are not aware of the content of drug boxes . Data eventually will be analyzed based on the Drugs box codes, selection of drug box will be random, and through balls and bags method . As a result, participants, observers have not any information about the drugs which patients will receive. Group 1: Epley maneuver with dimenhydrinate - Group 2: Epley maneuver with betahistine - Group 3: Epley maneuver with placebo. One week after epley maneuver, all patients undergoing hallpike maneuver. In the absence of nystagmus, the patients evaluated for symptoms such as light headedness, a feeling of floating, dizziness, ear fullness and weakness. DHI and Berg questionnaire to be filled for patients again.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201506231138N20**

Registration date: **2016-01-01, 1394/10/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-01, 1394/10/11

Registrant information

Name

Fataneh Bakhshi

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1223 8307

Email address

entrc@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Science, Vice Chancellor for Research

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-02-20, 1394/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Effect of betahistine and dimenhydrinate with Epley maneuver to improve symptoms in patients with benign paroxysmal positional vertigo

IR.GUMS.REC.1394.50

Public title

effect of betahistine and dimenhydrinate in benign paroxysmal positional vertigo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Unknown BPPV; Successful epley maneuver; Patients who don't receive any medication. Exclusion criteria: The inner ear disease; The inner or middle ear surgery; Migraine and headache during the study period; Using Psycho-neurological drugs during the study; The involvement more than one of a semi-circular canal; Re-Appearance of nystagmus after epley maneuver.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 120

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Guilan University of Medical Sciences

Street address

vice-chancellor for Research Building, opposite of Sepah Bank, Shahid Beheshti Blvd, Rasht

City

Rasht

Postal code

4139637459

Approval date

2015-06-16, 1394/03/26

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Benign paroxysmal vertigo

ICD-10 code

H81.1

ICD-10 code description

benign paroxysmal positional vertigo

Primary outcomes

1

Description

lightheadedness

Timepoint

Before starting the medication, and 1 week after starting drug

Method of measurement

Physical examination

2

Description

Diagnosis of BPPV

Timepoint

at the first study, One week after epley maneuver

Method of measurement

hallpike dix test

3

Description

feeling of floating

Timepoint

Before starting the medication, and 1 week after starting drug

Method of measurement

Physical examination

4

Description

dizziness

Timepoint

Before starting the medication, and 1 week after starting drug

Method of measurement

Physical examination

5

Description

ear fullness

Timepoint

Before starting the medication, and 1 week after starting drug

Method of measurement

Physical examination

6

Description

weakness

Timepoint

Before starting the medication, and 1 week after starting drug

Method of measurement

Physical examination

Secondary outcomes

1

Description

Quality of life

Timepoint

Before and after intervention

Method of measurement

The questionnaire Dizziness Handicap Inventory (DHI) and Berg balance scale (modified)

2

Description

daily activities

Timepoint

Before and after intervention

Method of measurement

The questionnaire Dizziness Handicap Inventory (DHI) and Berg balance scale (modified)

3

Description

disease severity

Timepoint

Before and after intervention

Method of measurement

The questionnaire Dizziness Handicap Inventory (DHI) and Berg balance scale (modified)

4

Description

emotional state

Timepoint

Before and after intervention

Method of measurement

The questionnaire Dizziness Handicap Inventory (DHI) and Berg balance scale (modified)

Intervention groups

1

Description

Intervention Group : Epley maneuver with dimenhydrinate

Category

Treatment - Drugs

2

Description

Intervention group : Epley maneuver with betahistine

Category

Treatment - Drugs

3

Description

Control Group : Epley maneuver with placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralamomenin Hospital

Full name of responsible person

Street address

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Guilan University of Medical Science, Vice Chancellor for Research

Full name of responsible person

Susan Komaee

Street address

vice-chancellor for Research Building, opposite of Sepah Bank, Shahid Beheshti Blvd, Rasht

City

Rasht

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Guilan University of Medical Science, Vice Chancellor for Research

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr Hooshang Gerami

Position

Professor

Other areas of specialty/work**Street address**

Amiralmomenin Hospital, 17 Shahrivar St, Rasht

City

Rasht

Postal code**Phone**

+98 13 3322 5242

Fax**Email**

hg_gerami@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Guilan University of Medical Sciences

Full name of responsible person

Dr Hooshang Gerami

Position

Professor

Other areas of specialty/work**Street address**

Amiralmomenin Hospital, 17 Shahrivar St., Rasht

City

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Postal code

4139637459

Phone

+98 13 3322 5242

Fax**Email**

hg_gerami@yahoo.com

Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty