

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 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 Resarch

##### 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**

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## Person responsible for scientific inquiries

### Contact

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**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*