Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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
IR.GUMS.REC.1394.50

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 Resarch
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 Resarch
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
Rasht
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