Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

The effects and side effects of Cinnarizine and Bethahistine in The Treatment of Patients with Acute Peripheral Vertigo

Protocol summary

Study aim
The effects and side effects of Cinnarizine and Bethahistine in The Treatment of Patients with Acute Peripheral Vertigo

Design
Double blind clinical trial with three parallel groups

Settings and conduct
The two drugs, Betahistine and cinnarizine, as well as the placebo drug from one Pharmaceutical Company were selected for study. There are no apparent differences between the three types of medications. Also, patients received the study received medicines for free. The study population included all patients with acute benign positional vertigo congestion after receiving informed consent and possible side effects if they were satisfied at the emergency department of Porsina Hospital of Rasht during 2019, in which the causes of central nervous system were rejected by neurological examinations and MRI. The severity of the symptoms is determined by the patient based on the visual grading scale (VAS), which range from "lack of symptoms" to "very severe symptoms

Participants/Inclusion and exclusion criteria
Inclusion criteria is : Age more than 18 years old, Age less than 60 years old patients referred with Benign Positional Vertigo (BPV), Did not use drug before reference, Meniere syndrome, Vertigo caused by untreated primary organ disease, Pregnancy, Patients use Benzodiazepines, CNS suppressant, Barbiturates, History of internal and middle ear surgery, Migraine headaches, Headache at the time of study, A history of mental or neurological illness Gastric ulcer and digestive problems

Intervention groups
The first group received 1 week treatment with cinnarizine 25 mg and placebo 3 times daily, and the second group received 1 week treatment with betahistine 8 mg and placebo 3 times a day and the third group received 1 week treatment with 1 betahistine And cinnarizine 3 times a day.

Main outcome variables
Feeling lightheaded

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130710013947N9**
Registration date: **2019-01-14, 1397/10/24**
Registration timing: **prospective**

Last update: **2019-01-14, 1397/10/24**
Update count: **0**

Registration date
2019-01-14, 1397/10/24

Registrant information

Name
Atta Mahdkhah

Name of organization / entity
Tabriz University of Medical Sciences

Country
Iran (Islamic Republic of)

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mshimia@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-02-20, 1397/12/01

Expected recruitment end date
2019-04-21, 1398/02/01

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effects and side effects of Cinnarizine and Bethahistine in The Treatment of Patients with Acute Peripheral Vertigo

Public title
The effects and side effects of Cinnarizine and Bethahistine in The Treatment of Patients with Acute Peripheral Vertigo
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age more than 18 years old Age less than 60 years old patients referred with Benign Positional Vertigo (BPV) Did not use drug before reference
Exclusion criteria:
Meniere syndrome Vertigo caused by untreated primary organ disease Pregnancy Patients use Benzodiazepines, CNS suppressant, Barbiturates History of internal and middle ear surgery Migraine headaches Headache at the time of study A history of mental or neurological illness Gastric ulcer and digestive problems
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients were randomly assigned to a study based on grading visits and inclusion criteria according to the required sample population. In the first of study, they were placed in a lacquer envelope and sealed in the research center. They were randomly assigned into 3 groups (betahistine and Placebo groups) Group B (Cinnarizine and Placebo Group) and Group C (Betahistine and cinnarizine) Random Allocation. The study blindness is done in such a way that random sequences are placed in closed envelopes at the nursing station, and the individual's in-person-based sequencing is carried out by the nurse of the department and the specialist does not know about the treatment. No information is available from the pocket. The nurse do not know anything about the illness level . The method of measuring vertigo symptoms is based on a questionnaire attached to the proposal (by a third person who has not played any role in the design of the research). Therefore, this study is a randomized, double blinded clinical trial study.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients were randomly assigned to a study based on grading visits and inclusion criteria according to the required sample population. In the first of study, they were placed in a lacquer envelope and sealed in the research center. They were randomly assigned into 3 groups (betahistine and Placebo groups) Group B (Cinnarizine and Placebo Group) and Group C (Betahistine and cinnarizine) Random Allocation. The study blindness is done in such a way that random sequences are placed in closed envelopes at the nursing station, and the individual's in-person-based sequencing is carried out by the nurse of the department and the specialist does not know about the treatment. No information is available from the pocket. The nurse do not know anything about the illness level . The method of measuring vertigo symptoms is based on a questionnaire attached to the proposal (by a third person who has not played any role in the design of the research). Therefore, this study is a randomized, double blinded clinical trial study.
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
Namjoo Street, Rasht, Guilan, Iran
City
Rasht
Province
Guilan
Postal code
4144666949
Approval date
2018-12-31, 1397/10/10
Ethics committee reference number
IR.GUMS.REC.1397.360

Health conditions studied

1

Description of health condition studied
Benign Positional Vertigo
ICD-10 code
H81.1
ICD-10 code description
Benign paroxysmal Positional vertigo

Primary outcomes

1

Description
Rate of positional vertigo
Timepoint
At first, 3rd days and 1 week later
Method of measurement
Visual Analog Scale

Secondary outcomes

1

Description
Significance improvement
Timepoint
3rd days and 1 week later after treatment
Method of measurement
Mean Vertigo Score (MVS)

Intervention groups

1

Description
Intervention group: The first group was treated with cinnarizine 25 mg and placebo 3 times a day
Category
Treatment - Drugs

2

Description
Intervention group: The second group received 1 week treatment with betahistine 8 mg and placebo 3 times a day
Category
Treatment - Drugs

3

Description
Intervention group: The third group was treated for 1 week with 1 betahistine 8 mg and cinnarizine 25 mg 3 times daily
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Poursina hospital of Rasht, Guilan University of Medical Sciences
Full name of responsible person
Dr Peyman Asadi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Rasht 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
Rasht University of Medical Sciences
Full name of responsible person
Dr Peyman Asadi
Position
Associate Professor
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Person responsible for updating data

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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
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
All data will published as article in journal without patients name
When the data will become available and for how long
After publication in journal
To whom data/document is available
After publication in journal
Under which criteria data/document could be used
After publication in journal
From where data/document is obtainable
It will be free or not depend on journal policy
What processes are involved for a request to access data/document
It will be free or not depend on journal policy
Comments