

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of cinnarizine and betahistine in the treatment of peripheral vertigo

Protocol summary

Study aim

Determination and Comparison of the Effect of cinnarizine and betahistine on the treatment of vertigo in patients referring to Imam Ali Hospital, Shahrekord

Design

A clinical trial without a parallel control group, single blind, randomized

Settings and conduct

They are randomly assigned to one of the two cinnarizine or betahistine groups. At the beginning of the study, all clinical and neurological examinations will be performed. Detection of environmental attack vertigo based on the onset of a patient's transient dizziness that causes round-head circumference, auditory symptoms, and the creation of vertical-spin nystagmus in a Dix-Hallpike maneuver.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Aged 18-65 years; having vertigo symptoms for at least two months; drug hypersensitivity to cinnarizine and betahistine; normal vital signs and findings; normal nerve examination; lack of control of vertigo control drugs at least 7 days ago; no evidence of evidence Causes of central dizziness in CT scan performed by the patient before the study begins; Exclusion criteria: Patients with abnormal vital signs, kidney failure, liver disease, heart disease, active stomach ulcer disease or diabetes; patients with ulcerative diagnosis of vertigo with central causes; brain injury due to trauma: simultaneous use of blood pressure medications such as thiazide, antihistamine, Corticosteroids and calcium channel antagonists; Patients who have been treated with benzodiazepines for any reason; Patients who have received anti-vertigo during the last week; The sensitivity of the drug to cinnarizine and betahistine; those who are pregnant or breastfeeding; those who are satisfied with Do not study

Intervention groups

We have two intervention groups. One receives betahistine and the other group receives cinnarizine.

Main outcome variables

Number of vertigo attacks

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171030037093N16**

Registration date: **2019-07-14, 1398/04/23**

Registration timing: **prospective**

Last update: **2019-07-14, 1398/04/23**

Update count: **0**

Registration date

2019-07-14, 1398/04/23

Registrant information

Name

Sadra Ansari pour

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3650 3487

Email address

st_ansari.s@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparison of cinnarizine and betahistine in the treatment of peripheral vertigo

Public title
The evaluation of the effect of cinnarizine and betahistine in the treatment of peripheral vertigo

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria:
Age 18-65 years old Having symptoms of vertigo for at least two months Non-sensitivity to cinnarizine and betahistine Natural Signs and Natural Nerve Findings Failure to receive vertigo control drugs at least 7 days before There is no evidence of the causes of central vertigo in a CT scan performed by a patient before the start of the study
Exclusion criteria:
Patients with abnormal vital signs, kidney failure, liver disease, heart disease, active stomach ulcer disease or diabetes Patients with ulcerative diagnosis of vertigo with central causes Brain traumatic brain injury Concomitant use of hypertension drugs such as thiazide, antihistamines, corticosteroids and calcium channel antagonists. Patients who are being treated for benzodiazepines for any reason Patients who have received anti-vertigo during the last week The sensitivity of the drug to cinnarizine and betahistine Those who are pregnant or breastfeeding People who are not satisfied with the study

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **170**

Randomization (investigator's opinion)
Randomized

Randomization description
The drugs are given without any code tags, and the patient selects one of the two randomly by choosing the code.

Blinding (investigator's opinion)
Single blinded

Blinding description
The drugs are given without any code tags and the patient selects one of two drugs randomly by choosing the code, and the name of each person and the prescription drug code is recorded by the secretary and the patient is not informed about the type of medication.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713492

Approval date

2018-07-22, 1397/04/31

Ethics committee reference number

IR.SKUMS.REC.1397.137

Health conditions studied

1

Description of health condition studied

peripheral vertigo

ICD-10 code

H81.3

ICD-10 code description

Other peripheral vertigo

Primary outcomes

1

Description

Number of vertigo attacks

Timepoint

Patients will be asked one week after the start of the study and 8 weeks after the start of the study

Method of measurement

vertigo symptom scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The first group receives 8 mg of betahistine three times a day

Category

Treatment - Drugs

2

Description

Intervention group: The second group received 25 mg of cinnarizine three times a day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Clinic

Full name of responsible person

Narges Maleki

Street address

Shariati Blvd., Imam Ali Clinic

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8816788640

Phone

+98 38 3224 2696

Email

Dr.safari@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahrekord University of Medical Sciences

Full name of responsible person

Dr. seyed Kamal Solati(Associate Professor of Psychology)

Street address

Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd

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Postal code

8815713471

Phone

+98 38 3334 2414

Email

kamal_solati@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Vice chancellor for research, Shahrekord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Mohammadhosein Saffari

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Neurology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Mohammadhosein Saffari

Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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Phone

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Email

Dr.safari@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

Information about the main outcome can be shared.

When the data will become available and for how long

Start the access period 4 months after publishing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Use data to complete clinical trial studies

From where data/document is obtainable

Imam Ali Clinic

What processes are involved for a request to access data/document

After the investigation of researcher request and presentation of required documents will be accessible.

Comments