# 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 Ansaripour

**Name of organization / entity**
Shahrekord University of Medical Sciences

**Country**
Iran (Islamic Republic of)

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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

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Chahar-Mahal-va-Bakhtiari

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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)

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

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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

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## Person responsible for updating data

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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**