

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of oral betahistine with intravenous diazepam in acute peripheral vertigo

Protocol summary

Summary

Background: Acute peripheral vertigo is a common complaint in emergency department and oligoanalgesia is a known phenomenon due to staff involvements and the chaotic environment of emergency department. Thus oral forms of drugs are the preferred forms in emergency departments. This trial compares the efficacy and safety of oral betahistine and intravenous diazepam in adult patients presenting in an academic emergency department with 50'000 patients annually. Participants: Inclusion criteria are patients over 18 years old with peripheral acute vertigo. Exclusion criteria are contraindications of diazepam and betahistine; advanced cardiac, pulmonary and cerebrovascular diseases. Intervention: First group will receive Betahistine and intravenous(IV) placebo and second group will receive oral placebo an IV Diazepam. Outcome: Symptom relief will be recorded in 0 and 6 hours after treatment and side effects will be recorded after 6 hours in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112208104N2**

Registration date: **2012-09-16, 1391/06/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-09-16, 1391/06/26

Registrant information

Name

Mohammad Amin Zare

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-01-01, 1389/10/11

Expected recruitment end date

2011-06-02, 1390/03/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral betahistine with intravenous diazepam in acute peripheral vertigo

Public title

Comparison of oral betahistine with intravenous diazepam in acute peripheral vertigo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients over 18 years old with peripheral acute vertigo Exclusion criteria: contraindications of diazepam and betahistine; advanced cardiac, pulmonary and cerebrovascular diseases.

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 100

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

Tehran University of Medical Sciences ethics committee

Street address

Deputy of research, Ghods street, Keshavarz Blvd, Tehran, Iran

City

Tehran

Postal code

144574311

Approval date

2010-08-20, 1389/05/29

Ethics committee reference number

133

Health conditions studied

1

Description of health condition studied

Acute peripheral vertigo

ICD-10 code

VIII

ICD-10 code description

Diseases of the ear and mastoid process

Primary outcomes

1

Description

Symptom control

Timepoint

0,2,4 and 6 hours after treatment

Method of measurement

Vertigo severity chart

Secondary outcomes

1

Description

Occurance of drug side effects

Timepoint

during the first 6 hours

Method of measurement

Monitoring the patient

Intervention groups

1

Description

beta histine 8 mg as treatment and stilled water 5 ml as placebo was given to first group

Category

Treatment - Drugs

2

Description

Diazepam 5 mg intravenous and oral placebo was given to second group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Rasool Hospital

Full name of responsible person

Mohammad Amin Zare

Street address

Niyayesh street, sattarkhan, tehran, iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran university of medical sciences; Deputy of research

Full name of responsible person

Shahin Akhoundzade

Street address

Poursina st, Keshavarz blv, Faculty of medicine

City

Tehran

Grant name

Grant code / Reference number

-

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran university of medical sciences; Deputy of 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

Tehran University of Medical Sciences

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Position

Assistant Professor

Other areas of specialty/work

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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