Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of oral betahistine with intravenous diazpam 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
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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 diazpam in acute peripheral vertigo

Public title
Comparison of oral betahistine with intravenous diazpam in acute peripheral vertigo
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: patiets over 18 yeras 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
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Poursina st, Keshavarz blv, Faculty of medicine
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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
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

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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