

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of oral Betahistine and intramuscular promethazine in treatment of acute peripheral vertigo in emergency department

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 intramuscular promethazine in adult patients presenting in an academic emergency department. Participants: Inclusion criteria are patients 18-65 years old with peripheral acute vertigo. Exclusion criteria are contraindications of promethazine and betahistine; pregnant and breast feeding women, central vertigo. Intervention: First group will receive Betahistine and intra muscle (IM) placebo and second group will receive oral placebo and IM promethazine. Outcome: Symptom relief will be recorded in 0 and 4 hours after treatment and side effects will be recorded after 4 hours in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062022834N1**

Registration date: **2015-07-11, 1394/04/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-07-11, 1394/04/20

Registrant information

Name

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Name of organization / entity

Jundishapur University of Medical sciences

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Recruitment status

Recruitment complete

Funding source

Jundishapur University of Medical Sciences

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-08-22, 1395/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral Betahistine and intramuscular promethazine in treatment of acute peripheral vertigo in emergency department

Public title

Comparison of oral Betahistine and intramuscular promethazine in treatment of acute peripheral vertigo in emergency department

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients aged 18-65 years old with peripheral acute vertigo. Exclusion criteria: contraindications of promethazine and betahistine; pregnant and breast feeding women; central vertigo.

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **160**

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

Jundishapur University of Medical Sciences

Street address

Jundishapur University of Medical sciences, Farvardin st., Golestan

City

Ahvaz

Postal code

Approval date

2015-05-23, 1394/03/02

Ethics committee reference number

ir.ajums.rec.1394.93

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, 1, 2 and 4 hours after treatment

Method of measurement

VAG score

Secondary outcomes

1

Description

Occurance of drug side effects

Timepoint

During the first 4 hours

Method of measurement

Monitoring the patient

Intervention groups

1

Description

Betahistine 8 mg as treatment and stilled water 2 ml as placebo was given to first group

Category

Treatment - Drugs

2

Description

Promethazine 25 mg intramuscle and oral placebo was given to second group

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Street address

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jundishapur University of Medical Sciences

Full name of responsible person

Nader Saki

Street address

Jundishapur University of Medical sciences, Farvardin st., Golestan

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Jundishapur University of Medical Sciences

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

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Full name of responsible person

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Web page address

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