Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Intravenous Promethazine Versus Diazepam for Treatment of Peripheral Vertigo in the Emergency Department

Protocol summary

Summary

This study is designed to compare the efficacy of intravenous Promethazine versus intravenous Diazepam for the treatment of Peripheral Vertigo in the Emergency Department . This study is a double blind randomized clinical trial conducted on 150 patients. Inclusion criteria: male and female patients aged 18 to 65 years with complaints of vertigo , Exclusion criteria: patients with central vertigo; Head Trauma; Pregnancy. Patients with a diagnosis of Acute Peripheral Vertigo were randomly divided into two groups A and B. to Group A intravenous Diazepam 5 mg and to group B 25 mg Promethazine intravenously injected. The intensity of vertigo in patients is determined by VAS tool. Efficacy in 30 minutes, 2 and 4 hours after drug administration are examined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015060122522N1**
Registration date: **2015-07-04, 1394/04/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-07-04, 1394/04/13

Registrant information

Name
Leila Shafipour
Name of organization / entity
Mazandaran University Of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Mazandaran University Of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Intravenous Promethazine Versus Diazepam for Treatment of Peripheral Vertigo in the Emergency Department

Public title

Intravenous Promethazine Versus Diazepam for Treatment of Peripheral Vertigo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Aged 18 - 65 years; Complaining of Vertigo ; There is not contraindication for intravenous promethazine and diazepam Exclusion criteria: Patient with centeral vertigo; Traumatic Brain Injury; Pregnant; Unable to provide informed consent

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: **150**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University Of Medical Sciences

Street address

Mazandaran

City

Sari

Postal code

Approval date

2015-06-01, 1394/03/11

Ethics committee reference number

IR.MAZUMS.REC.94.1175

Health conditions studied

1

Description of health condition studied

Vertigo

ICD-10 code

VIII

ICD-10 code description

Diseases of the ear and mastoid process

Primary outcomes

1

Description

Control Of Symptoms

Timepoint

30 minutes, 2 and 4 hours

Method of measurement

VAS

Secondary outcomes

empty

Intervention groups

1

Description

In group A , 5 mg of diazepam intravenously injected.

Category

Treatment - Drugs

2

Description

In group B , 25 mg of promethazine intravenously injected.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hospital

Full name of responsible person

Dr Golikhatir

Street address

Imam Hospital Emergency Department

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University Of Medical Sciences

Full name of responsible person

Dr Golikhatir

Street address

Imam Hospital

City

Sari

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr golikhatir

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for scientific 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