

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of diazepam and promethazine in relieving ataxia in patients with acute peripheral vertigo, a clinical trial

Protocol summary

Summary

Vertigo is among the most common reasons for emergency department visits, in which benign positional vertigo is a common etiology. Unlike repositioning maneuvers for the management of vertigo, evidence regarding drug therapy is very limited. This study aims to compare the effects of diazepam and promethazine in relieving ataxia in patients with acute peripheral vertigo. In a single blind clinical trial phase 3, seventy patients with acute peripheral vertigo and ataxia will be enrolled to the study. Patients were excluded from the study if any of the following criteria was present: syncope or cardiac event, central origin for vertigo, drug-induced vertigo or orthostatic hypotension, adverse reaction to diazepam and promethazine. Patients will be divided into two intervention groups using simple randomization, first arm, include 35 patients who receive 5 mg of intravenous diazepam and the second arm has also 35 patients who receive 12.5 mg of intramuscular promethazine. The patients will be reassessed 60 and 120 minutes after receiving the medication. The focus was on the effects of the medication on their ataxia, which was examined using both Romberg test and Tandem gait. Systolic and diastolic blood pressure as well as heart rate were measured and recorded. The patients were also questioned regarding any of the common medication side effects. The researchers will be masked about the study. The results of both groups will be compared with each other and statistically analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015120722777N2**

Registration date: **2015-12-26, 1394/10/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-12-26, 1394/10/05

Registrant information

Name

Abdolghader Pakniyat

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2014-08-28, 1393/06/06

Expected recruitment end date

2015-06-14, 1394/03/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of diazepam and promethazine in relieving ataxia in patients with acute peripheral vertigo, a clinical trial

Public title

treatment of ataxia in patients with acute peripheral vertigo.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: aged between 18-60 years old; acute peripheral vertigo and ataxia. exclusion criteria: history of syncope or cardiac event; considerations of a central origin for vertigo; focal neurological deficits; known pregnancy; evidence of drug-induced vertigo or orthostatic hypotension; known dystonic or adverse reaction to diazepam and promethazine or other similar agents; report of taking medication within 24 hours of ED presentation that might affect the results (e.g., antihistamines, antipsychotics, opioid analgesics or sedatives).

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Simple randomization was performed by using a random number table.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran

City

Arak

Postal code

Approval date

2014-09-17, 1393/06/26

Ethics committee reference number

93-167-1

Health conditions studied

1

Description of health condition studied

Acute peripheral vertigo

ICD-10 code

H81.1

ICD-10 code description

Benign paroxysmal vertigo

Primary outcomes

1

Description

Ataxia

Timepoint

60 and 120 minutes after intervention

Method of measurement

Romberg Test and tandem gait test

Secondary outcomes

1

Description

blood pressure

Timepoint

60 and 120 minutes after intervention

Method of measurement

Sphygmomanometer

2

Description

Heart Rate

Timepoint

60 and 120 minutes after intervention

Method of measurement

Pulse oximetry

Intervention groups

1

Description

Intervention 1: Patients with acute peripheral vertigo enroll to the study considering inclusion and exclusion criteria. First arm, include 35 patients who receive 5 mg of intravenous diazepam. The patients will reassessed 60 and 120 minutes after receiving the medication. The focus was on the effects of the medication on their ataxia, which was examined using both Romberg test and Tandem gait. Systolic and diastolic blood pressure as well as heart rate were measured and recorded. The patients were also questioned regarding any of the common medication side effects. The results of both groups will be compared with each other and statistically analyzed.

Category

Treatment - Drugs

2

Description

Intervention 2: Patients with acute peripheral vertigo enroll to the study considering inclusion and exclusion criteria. First arm, include 35 patients who receive 12.5 mg of intramuscular promethazine. The patients will reassessed 60 and 120 minutes after receiving the medication. The focus was on the effects of the medication on their ataxia, which was examined using both Romberg test and Tandem gait. Systolic and diastolic blood pressure as well as heart rate were measured and recorded. The patients were also questioned regarding any of the common medication side effects. The results of both groups will be compared with each other and statistically analyzed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-Asr Hospital

Full name of responsible person

Maryam Vakili

Street address

Vali-Asr Sq.

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person

Mohammad Rafiei

Street address

A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran

City

Arak

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, Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Maryam Vakili

Position

Resident

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Morteza Qaribi

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Assistant professor

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Person responsible for updating data

Contact**Name of organization / entity****Full name of responsible person**

Abdolghader Pakniyat

Position**Other areas of specialty/work**

Street address

City

Postal code

Phone

00

Fax

Email

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