

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

1. Comparing the effectiveness of intravenous promethazine and diazepam in treating peripheral vertigo in patients who have referred to Emergency Unit of Baqiatullah (may Allah hasten his honorable appearance) Hospital during the time span from 2015 to 2016

Protocol summary

Study aim

Promethazine and diazepam effectiveness in treating peripheral vertigo in patients who have referred to emergency unit of Baqiatullah (may Allah hasten his honorable appearance) Hospital has been evaluated

Design

The present study is a randomized clinical trial conducted on peripheral vertigo patients who have referred to Baqiatullah (may Allah hasten his honorable appearance) Hospital during the time span from 2015 to 2016

Settings and conduct

The patients completed the demographic information form and VAS (visual analog scale) questionnaire in such a manner that the patients were asked to score their intensity of vertigo with a number ranging from 1 to 10. Next, the patients were randomly assigned to two groups (based on random numbers table). Afterwards, the group one received intravenous promethazine for a dosage of 25 mg/ml and the second group was administered 5 mg/ml intravenous diazepam. The patients were asked to complete VAS form for a second time two hours after being administered with the drug. In case of developing drug-induced symptoms, they were recorded in the questionnaire form. Higher dosages of the same drugs were administered in case that the desired response to the drug was not acquired. Finally, the information obtained from the patients was analyzed by the study executor. The study was implemented in emergency unit of Baqiatullah (may Allah hasten his honorable appearance) Hospital

Participants/Inclusion and exclusion criteria

The eighteen-year-old individuals with peripheral vertigo who have referred to the emergency unit. The patients with the following conditions were discarded from the study: expression of dissatisfaction to continue with the

study, pregnant women, a history of allergy to the drugs administered in the study, taking antivertigo drugs during the past 24 hours, the development of signs of drug-induced dizziness, central vertigo symptoms and a history of traumatic brain injury. The aforementioned cases will be determined through self-report and examination

Intervention groups

17. Individuals with peripheral vertigo

Main outcome variables

The eighteen-year-old individuals with peripheral vertigo who have referred to the emergency unit

General information

Reason for update

Acronym

ipd

IRCT registration information

IRCT registration number: **IRCT20171221037984N1**

Registration date: **2018-02-06, 1396/11/17**

Registration timing: **retrospective**

Last update: **2018-02-06, 1396/11/17**

Update count: **0**

Registration date

2018-02-06, 1396/11/17

Registrant information

Name

ZOHREH NABIZADEH GHARGOZAR

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2269 2556

Email address

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

2015-03-21, 1394/01/01

Actual recruitment end date

2016-05-19, 1395/02/30

Trial completion date

empty

Scientific title

1. Comparing the effectiveness of intravenous promethazine and diazepam in treating peripheral vertigo in patients who have referred to Emergency Unit of Baqiatullah (may Allah hasten his honorable appearance) Hospital during the time span from 2015 to 2016

Public title

1. Comparing the effectiveness of intravenous promethazine and diazepam

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

7. The individuals, above 18 years of age, with motion sickness (peripheral vertigo) who have referred to emergency unit. The exclusion criteria are: expressing dissatisfaction to participate in the study, pregnant women, history of allergy to the drugs administered in the study, a history of taking antivertigo drugs during the past 24 hours, development of drug-induced motion sickness symptoms, existence of central vertigo and a history of traumatic brain injury. The abovementioned cases can be diagnosed in examinations and the patients' self-report

Exclusion criteria:

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **164**

Actual sample size reached: **164**

Randomization (investigator's opinion)

Randomized

Randomization description

9. In such a way that the patients are asked to score their intensity of vertigo in a range from one to ten. Next, the patients will be randomly assigned to two groups (by the use of random numbers table). Then, one group will

be treated by the use of intravenous promethazine (25 mg/ml) and the other will be subjected to IV diazepam (5mg/ml) treatment

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research and Ethics Committee Office of Shahid Beheshti University of Medical Sciences

Street address

Building Block One: No.5, ground floor, Medical Department, Shahid Beheshti Medical sciences University, Velenjak St., beside Taleqani Hospital, Tehran, Iran

City

tehran

Province

Tehran

Postal code

8156598765

Approval date

2016-03-30, 1395/01/11

Ethics committee reference number

IR-SBMU.MSP.REC.1395.385

2

Ethics committee

Name of ethics committee

Research and Ethics Committee Office of Shahid Beheshti University of Medical Sciences

Street address

31. Vanak Square, Baqiatullah (may Allah hasten his honorable appearance) Hospital

City

تهران

Province

Tehran

Postal code

8156598766

Approval date

2017-03-29, 1396/01/09

Ethics committee reference number

IR-SBMU.MSP.REC.1395.385

Health conditions studied

1

Description of health condition studied

Patients with peripheral vertigo

ICD-10 code

H81.3

ICD-10 code description

Other peripheral vertigo

Primary outcomes

1

Description

Vertigo Treatment

Timepoint

365 DAYS

Method of measurement

The Effectiveness OF Promethazine And Diazepam In
tThe Treatment Of Peripheral Vertigo

Secondary outcomes

1

Description

The individuals who had referred to the emergency unit were asked to complete the demographic characteristic and visual analog scale (VAS) forms; in such a way that the patients were asked to give a number from 1 to 12 to the intensity of vertigo they experience. In the next stage, the patients were randomly assigned to two groups (based on random numbers table). Afterwards, the first group was given IV promethazine (25 mg/ml) and the second group received IV diazepam (5mg/ml). The patients were asked to fill in the VAS form two hours after being administered with the drugs. The drug-induced symptoms, if any, were recorded in the questionnaire form. In case that the patients do not respond to the treatment favorably, a second dosage of the same drug will be prescribed.

Timepoint

25 and 5

Method of measurement

the first group was given IV promethazine (25 mg/ml) and the second group received IV diazepam (5mg/ml). The patients were asked to fill in the VAS form two hours after being administered with the drugs. The drug-induced symptoms, if any, were recorded in the questionnaire form. In case that the patients do not respond to the treatment favorably, a second dosage of the same drug will be prescribed

Intervention groups

1

Description

Intervention group: the peripheral vertigo individuals

who had referred to the emergency unit were subjected to treatment by IV promethazine for a dosage of 25mg/ml.

Category

Other

2

Description

Control group: the peripheral vertigo individuals who had referred to the emergency unit were subjected to treatment by IV diazepam for a dosage of 5mg/ml.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

The study was carried out in the emergency unit of Baqiatullah (may Allah hasten his honorable appea

Full name of responsible person

23. Dr. Kamran Haidari

Street address

Vanak Square, Baqiatullah (may Allah hasten his honorable appearance) Hospital

City

tehran

Province

Tehran

Postal code

7158896858

Phone

+98 21 2661 8710

Email

nabizadehfaezeh85@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Kamran Haidari

Street address

24. Vanak Square, Baqiatullah (may Allah hasten his honorable appearance) Hospital

City

tehran

Province

Tehran

Postal code

8156598765

Phone

+98 21 2661 8710

Email

Heidari-k@sbmu.ac.ir

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Kamran Haidari
Position
Emergency Medicine Associate Professor
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Tajrish Square, Shohaday-e-Tajrish Hospital
City
tehran
Province
Tehran
Postal code
7158896858
Phone
+98 21 2661 8710
Email
Heidari-k@sbmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr. Hamid Reza Javadzadeh
Position
Emergency Medicine Assistant Professor
Latest degree
Medical doctor
Other areas of specialty/work
Nursery
Street address
Vanak Square, Baqiatullah (may Allah hasten his honorable appearance) Hospital
City

tehran
Province
Tehran
Postal code
7158896859
Phone
+98 21 2661 8711
Email
nabizadehfaezeh85@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Sayyed Mohsen Fayyazi
Position
Emergency Medicine Resident
Latest degree
Medical doctor
Other areas of specialty/work
Nursery
Street address
Tajrish Square, Shohaday-e-Tajrish Hospital
City
tehran
Province
Tehran
Postal code
7158896862
Phone
+98 21 2661 8721
Email
mfayyazib@yahoo.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Research and Ethics Committee Office of Shahid Beheshti University of Medical Sciences

When the data will become available and for how long

100 DAY

To whom data/document is available

Dr. Kamran Haidari

Under which criteria data/document could be used

Dr. Kamran Haidari

From where data/document is obtainable

33. Sayyed Mohsen Fayyazi

What processes are involved for a request to access

data/document

Patients with peripheral vertigo

Comments