

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of oral piracetam and oral betahistine in treatment of acute vertigo in emergency department patients

Protocol summary

Summary

This is a non-blinded randomized clinical trial to compare oral betahistine and piracetam for treating outpatient vertigo patients. Patients with acute vertigo who are discharged from the emergency department will be included in the study. Patient who are below 18, are using other drugs that can improve vertigo, have prior history of sensitivity to each of two drugs, peptic ulcer disease, or pheochromocytoma, or are not consent to participate in the study will be excluded of this study. Target population for this study are patients with acute vertigo that are discharged from the emergency department. Sample size for this study is 96 (48 patients in each group). Patients will be randomly assigned to one of two groups (betahistine or piracetam group). Betahistine will be given 8 milligrams every eight hours and piracetam will be given 800 milligrams every eight hours. Both betahistin and piracetam will be given for seven days. Primary outcome is vertigo intensity after seven days. Secondary outcomes are nausea and fatigue intensity and adverse effects in two groups after seven days.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016011921063N3**

Registration date: **2016-08-28, 1395/06/07**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-28, 1395/06/07

Registrant information

Name

Arash Safaie

Name of organization / entity

Tehran University of Medical Scieces- Sina Hospital

Country

Iran (Islamic Republic of)

Phone

+98 216312413

Email address

a-safaie@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-09-01, 1394/06/10

Expected recruitment end date

2017-01-01, 1395/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of oral piracetam and oral betahistine in treatment of acute vertigo in emergency department patients

Public title

Comparison of oral piracetam and oral betahistine in treatment of acute vertigo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with acute vertigo who are discharged from the ED. Exclusion criteria: Age <18 years ; Prior sensitivity to piracetam or betahistin ; Using other drugs that potentially improve vertigo (antihistamines, anticholinergics, bezodiazepines, ...) ;

Peptic ulcer disease history ; Pheochromoytoma disease ;
Patients who are not consent to participate in the study

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences
ethical committee

Street address

Shahid Abbas Arabi street, Yemen Street, Shahid
Chamran Highway

City

Tehran

Postal code

Approval date

2015-08-25, 1394/06/03

Ethics committee reference number

IR.SBMU.SM.REC.1394.25

Health conditions studied

1

Description of health condition studied

Disorders of vestibular function

ICD-10 code

H81

ICD-10 code description

Disorders of vestibular function

Primary outcomes

1

Description

Vertigo severity

Timepoint

7 days after treatment

Method of measurement

NRS

Secondary outcomes

1

Description

Nausea intensity

Timepoint

7 days after treatment

Method of measurement

NRS

2

Description

Fatigue intensity

Timepoint

7 days after treatment

Method of measurement

NRS

3

Description

Adverse events

Timepoint

7 days after treatment

Method of measurement

Adverse event name

Intervention groups

1

Description

Piracetam 800 mg TDS PO

Category

Treatment - Drugs

2

Description

Betahistin 8 mg TDS PO

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hossein Hospital

Full name of responsible person

Dr Ali Arhami Dolatabadi

Street address

Emergency Department, Emam Hossein Hospital,
Shahid Madani street

City

Tehran

2

Recruitment center

Name of recruitment center

Shohada Tajrish Hospital

Full name of responsible person

Dr Saeed Safari

Street address

Tajrish square

City

Tehran

3

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Arash Safaie

Street address

Emergency Department, Sina Hospital, Hassan Abad
square

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

Street address

Shahid Abbas Arabi street, Yemen Street, Shahid
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City

Tehran

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

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Ali Arhami Dolatabadi

Position

Associate professor of emergency medicine

Other areas of specialty/work

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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