

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparative study of the effectiveness of promethazine with ondansetron in patients with acute peripheral vertigo

Protocol summary

Study aim

Comparison the effectiveness of promethazine and ondansetron in patients with acute peripheral vertigo

Design

randomized clinical trial, blinded, with a parallel group design of 170 patients. phase 3

Settings and conduct

This randomized comparative study was conducted in parallel groups to compare the therapeutic effect of ondansetron in comparison with muscle promethazine in 20-60 year old patients with acute peripheral vertigo referring to the emergency department of Porsina Hospital in Rasht Patients and evaporators were blind to treatments

Participants/Inclusion and exclusion criteria

Entry criteria: People aged between 20 and 60 years have signs of vertigo, including severe dizziness, an attack, nausea, vomiting, with and without previous hearing symptoms, such as tinnitus or ear forearm, lack of neurological symptoms New companion exit criteria: Dissatisfaction of Participation in the study. Coagulation disorders that lead to uncontrolled bleeding through injection. Based on history, patients with central dizziness, patients with signs and symptoms of benign paroxysmal positional vertigo(BPPV)) Have new central unilateral symptoms, recent trauma, pregnancy, evidence of dizziness due to adverse drug reactions, or loss of state of pressure, known dystrophy, or drug sensitivity to promethazine and ondansetron or similar drugs

Intervention groups

Patients referred to emergency department with acute peripheral vertigo were assigned to two groups A and B. To group A, promethazine 25 mg intramuscularly and 1 cc distilled water intravenously are injected . In group B, 4 ml of andonsetrone intravenously and 1 ml of distilled water intramuscularly are injected .

Main outcome variables

Introducing a drug that is used to treat vertigo that has

more effects and less complications than routine treatments.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180129038543N1**

Registration date: **2018-03-14, 1396/12/23**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-14, 1396/12/23**

Update count: **0**

Registration date

2018-03-14, 1396/12/23

Registrant information

Name

sara sutohian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3377 5940

Email address

ssutohian@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-24, 1396/08/02

Expected recruitment end date

2018-06-05, 1397/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effectiveness of promethazine with ondansetron in patients with acute peripheral vertigo

Public title

Assessing the effect of ondansetron on peripheral vertigo

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having acute peripheral vertigo Symptoms of vertigo include severe dizziness, attack with and without severe nausea age between 20-60 years

Exclusion criteria:

New associated neurological symptoms

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **170**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with the primary diagnosis of acute peripheral vertigo were assigned to two groups A and B randomly .The names of groups A and B were placed in a sealed envelope, and the nurse carried out the injection according to item A or B, which was in the envelope.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Selection of patients was based on the random allocation and the injection of medication by one of the emergency nurses of Pursina Hospital (MS) and the patients and the evaluator were blind with regard to the types of treatments.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Committee of Guilan University of Medical Sciences

Street address

No 28, Gilan Blvd, No 171, Golsar Str

City

Rasht

Province

Guilan

Postal code

4166734466

Approval date

2018-01-13, 1396/10/23

Ethics committee reference number

IR.GUMS.REC.1396.437

Health conditions studied**1****Description of health condition studied**

acute peripheral vertigo

ICD-10 code

H81.

ICD-10 code description

Disorders of vestibular function

Primary outcomes**1****Description**

Vertigo score in the questionnaire

Timepoint

Before injection; 30 minutes later and 2 hours after prescribing

Method of measurement

visual analogue scale, relieve score,questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

First intervention group: promethazine 25 mg muscular and 1 cc distilled water injected intravenously.before injection and after 30 minutes and 2 hours of drug administration patients were examined.

Category

Treatment - Drugs

2**Description**

Intervention group 2: intravenous ondronostron 4 mg and 1 cc distilled water injected muscularly. Patients are evaluated before injection and after 30 minutes and 2 hours of drug administration.

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Poursina Hospital

Full name of responsible person

Alia Saberi

Street address

Poursina Hospital, Poursina Cross

City

Rasht

Province

Guilan

Postal code

1319441937

Email

ssutohian@gmail.com

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Shadman Nemati

Street address

Poursina hospital, Poursina cross

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Province

Guilan

Postal code

41937-13194

Email

ssutohian@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Rasht University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

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**

Rasht University of Medical Sciences

Full name of responsible person

Sara Sutohian

Position

General practitioner

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

the data are secret

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Anonymous completed questionnaires

When the data will become available and for how long

3 months after publication of the results

To whom data/document is available

only memberships of neurology and otolaryngology groups of Guilan University of Medical Sciences

Under which criteria data/document could be used

If we are involved as a contributor in their essay and paper

From where data/document is obtainable

Dr. Alia Saberi-Rasht - Guilan University of Medical Sciences - Neuroscience Research Center - alia.saberi.1@gmail.com

What processes are involved for a request to access data/document

sending by email

Comments