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

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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, reliefe 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 centers

1

Recruitment center
Name of recruitment center
Poursina Hospital
Full name of responsible person
Alia Saberi
Street address
Poursina Hospital, Poursina Cross
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht University of Medical Sciences
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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 practitionor
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 Guialn University of Medica 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