Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jun 2026

A clinical trial of sublingual Rizatriptan versus oral Betahistin in acute phase treatment of vertigo in patients suffering from vestibular migraine

Protocol summary

Study aim
Comparison of the effect of using rizatriptan with Betahistine in the treatment of the acute phase of vertigo in outpatients with vestibular migraine referred to a private clinic.

Design
A double blinded parallel group phase 3 clinical trial with 40 patients randomized with www.Randomization.com site.

Settings and conduct
The present study will be a clinical trial designed to compare the effectiveness of rizatriptan and Betahistine in the treatment of vertigo in patients with vestibular migraine in its acute phase. About 40 patients with a history of vestibular migraine who present with vertigo to a private neurology or otolaryngology clinic will be selected based on the diagnostic criteria of vestibular migraine of the International Headache Society and entered the study randomly based on the inclusion and exclusion criteria. And will be divided into two groups A (the group receiving rizatriptan oral 10 mg) and group B(receiving Betahistine 8 mg) and will be evaluated and compared after two hours and 24 hours after receiving the drugs, respectively, in terms of the severity of dizziness and the response rate to the treatment.

Participants/Inclusion and exclusion criteria
Including the criteria of the International Headache Society for vestibular migraine; presence of acute vertigo with moderate to severe intensity at the time of visit, age 18 to 6. Exclusion criteria: History of basilar or hemiplegic migraine: presence of severe kidney and liver disorders; symptoms suggestive of ischemic heart disease or history of cardiovascular diseases and history of stroke or TIA; systolic blood pressure above 160 or diastolic blood pressure above 90; pregnancy; Lack of consent to participate in the study

Intervention groups
Group A (receiving oral rizatriptan 10 mg) and group B (group receiving Betahistine 8 mg)

Main outcome variables
Dizziness severity, Response rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230913059428N1**
Registration date: **2023-10-09, 1402/07/17**
Registration timing: **prospective**

Last update: **2023-10-09, 1402/07/17**
Update count: **0**

Registration date
2023-10-09, 1402/07/17

Registrant information

Name
Venus Ghaffarzadeh Farid

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 41 3658 2544

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v.ghaffarzadeh@tbzmed.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-23, 1402/08/01

Expected recruitment end date
2024-10-22, 1403/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A clinical trial of sublingual Rizatriptan versus oral Betahistin in acute phase treatment of vertigo in patients suffering from vestibular migraine

Public title
Rizatriptan versus Betahistin in Vestibular Migraine treatment

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Including the International Headache Society criteria for vestibular migraine Acute vertigo with moderate to severe intensity

Exclusion criteria:
Patients with suspected vestibular disorders other than vestibular migraine Patients with a suspected history of Orthostatic Hypotension or panic disorders history of basilar or hemiplegic migraine Presence of severe kidney or liver disorders Symptoms suggestive of ischemic heart disease history of HTN history of previous TIA/stoke history of drug or substance or alcohol abuse Systolic blood pressure above 160 or diastolic blood pressure above 90 pregnancy

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples eligible for study will be randomly assigned to two treatment groups with oral rizatriptan or Betahistine treatment using www.Randomization.com.

Blinding (investigator's opinion)
Double blinded

Blinding description
Both the patients and all the researchers (ear, nose and throat specialist, neurologist, neurology resident, statistical consultant) will be unaware of the patient's exposure (Betahistine or Rrizatriptan).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Working group/committee of ethics in research of Tabriz University of Medical Sciences

Street address
No.74,Dastmalchi Alley., Abbasi Ave., , Tabriz

City
Tabriz

Province
East Azarbaijan

Postal code
5155734831

Approval date
2023-10-07, 1402/07/15

Ethics committee reference number
IR.TBZMED.REC.1402.510

Health conditions studied

1

Description of health condition studied
vestibular migraine

ICD-10 code
G43

ICD-10 code description
Migraine

2

Description of health condition studied
vestibular migraine

ICD-10 code
H81.8X

ICD-10 code description
Other disorders of vestibular function

Primary outcomes

1

Description
dizziness intensity

Timepoint
At the beginning of the study (before the start of the intervention) and 4 and 24 hours after taking the drug

Method of measurement
Compiled questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: (The first intervention group) patients in this group will receive oral rizatriptan 10 mg (Farabi Pharmaceuticals) once as a stat dose.
Category
Treatment - Drugs

2

Description
Intervention group: (second intervention group): Patients of this group will receive oral Betahistine 8 mg (Actoverco Pharmaceuticals) once as a stat dose.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Aban Otolaryngology Clinic
Full name of responsible person
venus Ghaffarzadeh Farid
Street address
No.74,. Dastmalchi Alley, Abbasi Ave., before Tavanir Blvdabriz
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Sponsors / Funding sources

1

Sponsor
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Tabriz 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
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Venus Ghaffarzadeh Farid
Position
Neurology Resident
Latest degree
Medical doctor
Other areas of specialty/work
Neurology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available