

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)

Phone

+98 41 3658 2544

Email address

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/stroke 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 Rizatriptan).

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

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

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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

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v.ghaffarzadeh@tbzmed.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Venus Ghaffarzadeh Farid

Street address

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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 scientific inquiries

Contact

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Position

Neurology resident

Latest degree

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

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Full name of responsible person

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Position

Neurology resident

Latest degree

Medical doctor

Other areas of specialty/work

Neurology

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City

Tabriz

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