

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of Epley therapy in patients with benign paroxysmal positional vertigo

Protocol summary

Study aim

Investigating the effect of Epley therapy in patients with benign paroxysmal positional vertigo

Design

Non-blind phase 2 clinical trial. Available sampling method is used. In this way, people will be selected based on the entry criteria from among the people who refer to Matini Hospital in Kashan. Then, the samples will be assigned to two intervention and control groups by block randomization using Excel software in the form of 7 quadruple blocks, and 35 people will be placed in each group.

Settings and conduct

Non-blind phase 2 clinical trial. Available sampling method is used. In this way, people will be selected based on the entry criteria from among the people who refer to Matini Hospital in Kashan. Then, the samples will be assigned to two intervention and control groups by block randomization using Excel software in the form of 7 quadruple blocks, and 35 people will be placed in each group.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1- Having informed consent to enter the study 2- Absence of other diseases involving the vestibule 3- Absence of pregnancy Exclusion criteria 1- Lack of cooperation with the researcher 2- having systemic diseases such as diabetes, blood pressure, acute cardiovascular disease, active connective tissue disorder, chronic kidney disease and chronic liver disease 3- Patients suffering from central dizziness 4- BBPV sufferers whose type of involvement is not of the posterior canal type. 5- People suffering from psychological diseases

Intervention groups

Intervention: People who receive Epley's maneuver in addition to betahistine No intervention: subjects receiving only betahistine

Main outcome variables

Severity of BPPV symptoms based on DHI questionnaire

at the beginning of the study, on the 3rd day, 7th day and at the end of the 4th week

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240514061802N1**

Registration date: **2024-07-17, 1403/04/27**

Registration timing: **prospective**

Last update: **2024-07-17, 1403/04/27**

Update count: **0**

Registration date

2024-07-17, 1403/04/27

Registrant information

Name

Nargess Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8805 5345

Email address

narsis.mo1378@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-08-22, 1403/06/01

Expected recruitment end date

2025-03-19, 1403/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Epley therapy in patients with benign paroxysmal positional vertigo

Public title

the effect of Epley therapy in patients with benign paroxysmal positional vertigo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having informed consent to enter the study Not suffering from other diseases involving the vestibule Absence of pregnancy

Exclusion criteria:

Patients with central vertigo Patients with BBPV whose type of involvement is not of the posterior canal type. People with psychological diseases Having systemic diseases such as diabetes, hypertension, acute cardiovascular disease, active connective tissue disorder, chronic kidney disease, and chronic liver disease. Lack of cooperation with the researcher

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be assigned to two intervention and control groups by block randomization using Excel software in the form of 7 quadruple blocks, and 35 people will be placed in each group.

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

Ethics Committee of Kashan University of Medical

Sciences

Street address

Kashan - Qutb Rawandi Boulevard - Kashan University of Medical Sciences

City

Kashan

Province

Isfahan

Postal code

8715981151

Approval date

2024-06-01, 1403/03/12

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1403.032

Health conditions studied

1

Description of health condition studied

سرگیجه ی حمله ای خوش خیم وضعیتی

ICD-10 code

HB1.1

ICD-10 code description

Benign paroxysmal vertigo

Primary outcomes

1

Description

Severity of BPPV symptoms

Timepoint

at the beginning of the study, on the 3rd day, 7th day and the end of the 4th week

Method of measurement

DHI questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients receiving epley manœuvre in addition to betahistine

Category

Treatment - Drugs

2

Description

Control group: patients receiving betahistine alone

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Matini hospital

Full name of responsible person

Nargess Mohammadi

Street address

Amir kabir street,Matini hospital,kashan

City

Kashan

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Isfahan

Postal code

8719674591

Phone

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Fax

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Email

matinihospital@kaums.ac.ir

Web page address

<https://matini.kaums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Amir hosein Ahsani

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Email

amirhosein.ahsani1397@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Nargess Mohammadi

Position

intern

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Amir hosein Ahsani

Position

دانشیار

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for updating data

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Position

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Latest degree

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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