

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Semont and Epley's maneuver in Patients with benign paroxysmal positional vertigo

Protocol summary

Study aim

To compare the effects of Semont and Epley's maneuver in patients with Benign Paroxysmal Positional Vertigo (BPPV) using Patient Specific functional scale and Activity based Confidence (ABC) scale

Design

Randomized Control Trial RCT, Single blind study Study groups: Epley's and Semont group Phase: N.A Sample size : 24 Randomization: In this study simple random sampling technique is used by sealed envelop method by using a computerized random number generator. The study is single blinded as participants is not aware of the intervention group they are placed in. Study center: Single center study

Settings and conduct

Health care unit in Islamabad (ENT department) In this study simple random sampling technique is used by sealed envelop method by using a computerized random number generator. The study is single blinded as participants is not aware of the intervention group they are placed in.

Participants/Inclusion and exclusion criteria

Inclusion criteria: • Diagnosed Benign paroxysmal positional vertigo • Patients with recurrent rotatory vertigo attacks proceeded by rapid and/or gravity-dependent head movements • Patients with active daily life activities between ages 20 to 65 years • Patients having positional dizziness Exclusion criteria: • Patients who have any neuromuscular comorbidity • Patients on any kind of drug or sedative during study • Patients with epilepsy or on epileptic drugs • Patient with highly impaired vision • Bilateral Benign paroxysmal positional vertigo

Intervention groups

There are 2 groups . 1. Epley's Group 2. Semont Group

Main outcome variables

1. Patient specific functional scale to evaluate functional scale 2. Activity based confidence scale to evaluate confidence level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211022052835N1**

Registration date: **2021-12-01, 1400/09/10**

Registration timing: **retrospective**

Last update: **2021-12-01, 1400/09/10**

Update count: **0**

Registration date

2021-12-01, 1400/09/10

Registrant information

Name

Fouzia Batool

Name of organization / entity

Shifa Tameer-e-Millat University

Country

Pakistan

Phone

+92 51 8441752

Email address

fouzia_dpt.ahs@stmu.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-05, 1400/01/16

Expected recruitment end date

2021-07-01, 1400/04/10

Actual recruitment start date

2021-04-14, 1400/01/25

Actual recruitment end date

2021-08-08, 1400/05/17

Trial completion date

2021-08-08, 1400/05/17

Scientific title

Comparison of Semont and Epley's maneuver in Patients with benign paroxysmal positional vertigo

Public title

Comparison of Semont and Epley's maneuver in vertigo

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosed Benign paroxysmal positional vertigo Patients with active daily life Activities between ages 25 to 65 years Patients having positional dizziness Patients with recurrent rotatory vertigo attacks proceeded by rapid and/or gravity-dependent head movements

Exclusion criteria:

Patients who have any neuromuscular comorbidity Patients on any kind of drug or sedative during study Patients with epilepsy or on epileptic drugs Patient with highly impaired vision Bilateral Benign paroxysmal positional vertigo

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **56**

Actual sample size reached: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study simple random sampling technique is used by sealed envelop method by using a computerized random number generator. The sequence of random allocation is done by an individual who has not directly involved in the study. Random numbers is written on index cards and placed in thick and opaque sealed envelopes before the study. After taking consent from the patient for their participation in the study, the therapist opens the envelop and give the respective treatments to the patients . The study is single blinded as participants is not aware of the intervention group they are placed in.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants are single blinded as they don't know which treatment plan or intervention is given to them.

Placebo

Not used

Assignment

Parallel

Other design features

N/A

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Institutional review board and ethical committee shifa tameer-e-millat and shifa international hospi

Street address

Pitras Bukhari Road, Shifa international hospital Ltd. sector h-8/4 Islamabad

City

Islamabad

Postal code

44790

Approval date

2021-04-01, 1400/01/12

Ethics committee reference number

IRB#08-21

Health conditions studied

1

Description of health condition studied

Benign paroxysmal positional vertigo is a spinning sensation in head that leads to vertigo and dizziness. it can be treated with rehabilitative techniques and positioning maneuvers.

ICD-10 code

H81.10

ICD-10 code description

Benign paroxysmal positional vertigo, unspecified ear

Primary outcomes

1

Description

To compare the effects of Semont and Epley's maneuver in patients with BPPV using Patient Specific functional scale and Activity based Confidence scale

Timepoint

Single session, before and after treatment

Method of measurement

Patient specific functional scale and Activity based confidence scale

Secondary outcomes

1

Description

To determine the effects of Semont and Epley's maneuver in patients with BPPV using Patient Specific functional scale and Activity based confidence scale

Timepoint

Single session, before and after treatment

Method of measurement

Patient specific functional scale and Activity based confidence scale

Intervention groups

1

Description

Intervention group1 : Epley's Group is given Epley's maneuver has sequential movement of the head into four positions staying in each position for roughly 30 seconds. It includes supine lying, 45 degree head rotation, head extension , head rotation and then sitting. It is intended to move debris or "ear otoconia" out of the sensitive part of the ear (posterior canal) to a less sensitive location. It is also sometimes called the "canalith repositioning maneuver".

Category

Rehabilitation

2

Description

Intervention group 2: Semont Group is given Semont maneuver in which patient sit on the edge of bed. First patient head is turned 45 degrees to the right and then quickly lie down him on left side. This position is maintained for 30 seconds. And then the patient is quickly move to lie down on the opposite end of the bed. After that return him slowly to sitting and wait a few minutes.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Pakistan Atomic energy commision (PAEC) General hospital

Full name of responsible person

Shiza Rizwan

Street address

M238+2JC ,H-11/4Islamabad .

City

Islamabad

Postal code

46100

Phone

+92 51 9271716

Fax

Email

shizarizwan2@gmail.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shifa Tameer-e-Millat University

Full name of responsible person

Fouzia Batool

Street address

Pitras Bukhari Road, Shifa Tameer-e-Millat University, H-8/4, Islamabad

City

Islamabad

Postal code

44000

Phone

+92 51 8441752

Email

fouzia_dpt.ahs@stmu.edu.pk

Grant name

Grant code / Reference number

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

No

Title of funding source

Shifa Tameer-e-Millat University

Proportion provided by this source

100

Public or private sector

Private

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

Shifa Tameer-e-Millat University

Full name of responsible person

Fouzia Batool

Position

Assistant Professor

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

Pitras Bukhari Road, Shifa Tameer-e-Millat University, H-8/4, Islamabad

City

Islamabad

Province

Punjab

Postal code

44000

Phone

+92 332 7120385

Fax

Email

fouzia_dpt.ahs@stmu.edu.pk

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shifa tameer-e- millat university islamabad

Full name of responsible person

Shiza Rizwan

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

House no :44, St :05 ,british homes I-12 Islamabad

City

Islamabad

Province

Punjab

Postal code

46060

Phone

+92 336 5498116

Email

shizarizwan2@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shifa tameer-e- millat university islamabad

Full name of responsible person

Shiza Rizwan

Position

Student

Latest degree

Master

Other areas of specialty/work

Physiotherapy

Street address

House no :44, St :05 ,british homes i-12 Islamabad

City

Islamabad

Province

punjab

Postal code

46060

Phone

0336498116

Email

shizarizwan2@gmail.com

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

There is no further information

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

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Comparison of Semont and Epley's maneuver in patients with benign paroxysmal positional vertigo

When the data will become available and for how long

Data will not be available

To whom data/document is available

There is no such plan

Under which criteria data/document could be used

There is no such plan

From where data/document is obtainable

shizarizwan2@gmail.com

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

Applicant can apply through email for any help or detail of the study and responses will be provided through email in a day or twice.

Comments