Comparison of the vestibulo-ocular reflex in patients with posterior semicircular canal benign paroxysmal positional vertigo before and after rehabilitation treatment assessed by video head impulse test

Protocol summary

Summary
(1) Objectives: to evaluate vestibule-ocular reflex in each semicircular in patients with posterior semicircular canal benign paroxysmal positional vertigo (PSC-BPPV) before and after rehabilitation maneuver, (2) Design: non-randomized clinical trial, (3) Setting: Vertigo Rehabilitation Clinic, Audiology Department, Tehran University of Medical Sciences, Iran, (4) Participants: thirty patients with PSC-BPPV, (5) Method: measurement of vestibule-ocular reflex (VOR) by vHIT in patients before and after Epley maneuver, (6) Intervention: Epley maneuver, (7) Main outcomes: VOR gain, gain asymmetry, saccades.

General information

Acronym
IRCT registration information
IRCT registration number: IRCT2016013126279N1
Registration date: 2016-04-26, 1395/02/07
Registration timing: registered_while_recruiting

Recruitment status
Recruitment complete

Funding source
Tehran University of Medical Sciences (TUMS)

Expected recruitment start date
2016-01-21, 1394/11/01

Expected recruitment end date
2016-06-20, 1395/03/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the vestibulo-ocular reflex in patients with posterior semicircular canal benign paroxysmal positional vertigo before and after rehabilitation treatment assessed by video head impulse test

Public title
Effects of rehabilitation treatment on vestibulo-ocular reflex

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: posterior semicircular canal benign paroxysmal positional vertigo; no other vestibular disorders; no cervical problem; no peripheral disorder in the right eye. Exclusion criteria: reluctant to cooperation during treatment sessions; no vertigo release after second rehabilitation session; occurrence of other vestibular disorders during study; feeling pain in cervical area during vHIT; nausea or vomiting during vHIT.

Age
No age limit

Gender
Both
Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 30

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences (TUMS)

Street address
Enqelab Ave.

City
Tehran

Postal code

Approval date
2015-11-22, 1394/09/01

Ethics committee reference number
IR.TUMS.REC.1394.1210

Health conditions studied

1

Description of health condition studied
Benign paroxysmal positional vertigo

ICD-10 code
H81.1

ICD-10 code description
Benign paroxysmal vertigo

Primary outcomes

1

Description
Mean vestibulo-ocular reflex gain in each semicircular canal

Timepoint
Before and after treatment

Method of measurement
ICS impulse (GN Otometrics, USA)

Secondary outcomes
empty

Intervention groups

1

Description
With the patient sitting upright, the head is turned 45 degrees to the patient's affected side. The patient is then moved from the sitting position to the supine position with the head hanging below the top end of the examination table at an angle of 20 degrees. The head is turned 90 degrees toward the unaffected left side. The head is then turned another 90 degrees, to a face-down position, and the trunk is turned 90 degrees in the same direction, so that the patient is lying on the unaffected side. The patient is then moved to the sitting position. Each position should be maintained until the induced nystagmus and vertigo resolve, but always for a minimum of 30 seconds. The rehabilitation procedure is performed in maximum two sessions (with one week interval).

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Vestibular assessment clinic, School of Rehabilitation, Tehran University of Medical Sciences (TUMS)

Full name of responsible person
Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Tehran University of Medical Sciences (TUMS)
Full name of responsible person
Shabnam Noroozzadeh
Street address
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City
Tehran
Grant name

Is the source of funding the same sponsor/organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences (TUMS)
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries
Contact
Name of organization / entity
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Full name of responsible person
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Sharing plan
Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty