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: Eply 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

**Other design features**

<table>
<thead>
<tr>
<th>Secondary IDs</th>
<th>empty</th>
</tr>
</thead>
</table>

**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 vetibulo-ocular reflex gain in each semicircular canal

**Timepoint**
before and after treatment

**Method of measurement**
ICS impulse (GN Otometrics, USA)

2

**Description**
Covert saccades

**Timepoint**
before and after treatment

**Method of measurement**
ICS impulse (GN Otometrics, USA)

3

**Description**
Overt saccades

**Timepoint**
before and after treatment

**Method of measurement**
ICS impulse (GN Otometrics, USA)

4

**Description**
Gain symmetry

**Timepoint**
before and after treatment

**Method of measurement**
calculation

**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**
Vestibular assessment clinic, School of Rehabilitation, Tehran University of Medical Sciences (TUMS)

**Full name of responsible person**
Sponsors / Funding sources

1

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

Title of funding source: Tehran University of Medical Sciences (TUMS)
Proportion provided by this source: 100%

Person responsible for general inquiries

Contact
Name of organization / entity: Tehran University of Medical Sciences (TUMS)
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Person responsible for scientific inquiries

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City: Tehran
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Fax: Email: madel@tums.ac.ir
Web page address:

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