Benign paroxysmal position vertigo after traumatic brain injury.

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The primary objective is to clarify the frequency of t-BPPV in patients after mild TBI. Secondary objectives are: assessment of the symptoms of t-BPPV and the treatment success of t-BPPV.

Ethical review	Approved WMO
Status	Pending
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Observational non invasive

Summary

ID

NL-OMON51263

Source
ToetsingOnline

Brief title
BPPV After Trauma (BAT) study

Condition

- Inner ear and VIIIth cranial nerve disorders
- Head and neck therapeutic procedures

Synonym
Dizziness

Research involving
Human

Sponsors and support

Primary sponsor: Gelre Ziekenhuizen
Source(s) of monetary or material Support: Gelre wetenschapsfonds;toegekende subsidie bedraagt ¤22.640

Intervention

Keyword: Benign paroxysmal position vertigo, BPPV, Canalith repositioning manoeuvres, Traumatic brain injury

Outcome measures

Primary outcome

The primary study parameter is the frequency of t-BPPV after mild TBI.

Secondary outcome

Secondary study parameters are: 1. The symptoms and characteristics of t-BPPV.

2. The treatment success of CRM treatment in terms of resolution of symptoms

and the recurrence rate after one year follow up in patients with t-BPPV.

Study description

Background summary

Benign Paroxysmal Positional Vertigo (BPPV) is one of the most common vestibular disorders. Patients with BPPV suffer from vertigo after movements of the head, increasing the risk of falling. BPPV can be very effectively treated by a canalith repositioning manoeuvre (CRM). The majority of cases of BPPV is idiopathic. Secondary BPPV can be related to traumatic brain injury (TBI) or inner ear disorders. Dizziness affects a large proportion of head injured patients and may persist for many years after the injury. Therefore, it is important to investigate ways to facilitate early diagnosis and management of dizziness and imbalance after head injury and identify the patients suffering from traumatic-BPPV (t-BPPV). Currently there is no data on the frequency and type of BPPV in acute TBI and contradictory data about the recurrence of t-BPPV. The main aim of this study is to accurately determine the frequency of BPPV after TBI. Secondary aims are to address: (1) the symptoms and characteristics of t-BPPV. Is there a **subclinical** type of BPPV (without symptoms)? (2) determine the treatment success of t-BPPV and (3) determine the recurrence rate of t-BPPV. We hypothesize that the frequency of BPPV is higher after a TBI than reported in previous studies, because of underdiagnosis and absence of symptoms.

Study objective

The primary objective is to clarify the frequency of t-BPPV in patients after mild TBI. Secondary objectives are: assessment of the symptoms of t-BPPV and the treatment success of t-BPPV.

Study design

A prospective, single-center, observational cohort study.

Intervention

All patients will be tested for t-BPPV by means of Dix-Hallpike and Supine roll tests and treated if necessary with a CRM.

Study burden and risks

If patients consent to enter the study, they will be invited to visit the ENT/Neurology department of Gelre Hospital one week after trauma. The included patients will be asked to fill in two questionnaires regarding their symptoms, the severity of vertigo and the impact of dizziness on their quality of life. Patients will be tested for BPPV by means of Dix-Hallpike and Supine roll tests. All patients with confirmed t-BPPV will be treated with a CRM. There will be an one year follow up after trauma. No other extra procedures will be performed for the study (no invasive procedures, clinical tests, laboratory tests etc.).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Older than 18 years
- Mild traumatic brain injury (with or without a CT scan)

Exclusion criteria

- Patient does not speak English or Dutch
- Cervical spine ligament injury or fracture

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2021
Enrollment:	196
Type:	Anticipated

Ethics review

Approved WMO Date:	25-03-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL75988.058.20