Benign Paroxysmal Positional Vertigo in the Elderly with an Increased Risk of Fall Incidents

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To determine the prevalence of BPPV in the elderly patients with an increased risk of fallsSecondary ObjectivesTo compare the outcomes within BPPV patients before and after successful treatment with a canalith repositioning manoeuvre (CRM):* The...

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

Summary

ID

NL-OMON46283

Source
ToetsingOnline

Brief title
BELFIN

Condition

- Inner ear and VIIIth cranial nerve disorders

Synonym
Benign Paroxysmal Positional Vertigo/Positional Dizziness

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: BPPV, Elderly, Fall Incidents, Vertigo

Outcome measures

Primary outcome

Primary outcome

The occurrence of definitive or possible BPPV after performing a diagnostic manoeuvre according to the *Consensus Document of the Committee for the Classification of Vestibular Disorders of the Bárány Society*.

Definitive BPPV

o Recurrent attacks of positional vertigo or positional dizziness provoked by a diagnostic manoeuvre.

o Duration of attacks in most cases <1min.

o Positional nystagmus elicited after a latency of one or few seconds by a diagnostic manoeuvre.

o Not attributable to another disorder.

Possible BPPV

It is reasonable that the amount of otoconia in the semi-circular canal is sufficient to evoke subjective symptoms but insufficient to stimulate the vestibulo-ocular reflex.

o Recurrent attack of positional vertigo or positional dizziness provoked by a diagnostic manoeuvre.

o Duration of attacks in most cases <1min.

o No positional nystagmus objectified by diagnostic manoeuvres.

Secondary outcome

1. Fall incidents

To compare the severity and amount of fall incidents before and after successful treatment for BPPV and between patient groups, an evaluation of fall incidents 6 months prior and 6 months after treatment will be performed.
At the time of diagnosis and treatment (visit 0) a self-administered questionnaire (See Appendix 14.4) will be taken. The vestibular technician who performs the diagnostic and therapeutic repositioning manoeuvres will answer questions about presence, type, affected side and canal of BPPV. Subjects will receive a self-administered diary to record every single fall incident (see Appendix 14.5).

2. Hospital Anxiety and Depression Scale

To evaluate the effect of anxiety or depression on the recurrence rate and number of CRM*s needed the HADS will be used (See Appendix 14.3). The HADS was developed by Zigmond and Snaith in 1983 and is often used to detect states of depression and/or anxiety in the setting of a hospital medical outpatient clinic. The HADS was validated in different Dutch subjects by Spinhoven et al. in 1997.
Points for questions regarding anxiety and depression are separately calculated. Cut-off values for both anxiety and depression include:
- Score 8-10: mild problems regarding anxiety or depression

- Score 11-14: moderate problems regarding anxiety or depression

- Score 15-21: severe problems regarding anxiety or depression

Recurrence will be defined as the occurrence of definitive or possible BPPV after successful treatment within one year.

3. Quality of life

To evaluate the quality of life before and after treatment, between patients with and without BPPV and to evaluate the effect of the quality of life score on the recurrence rate and number of CRM*s needed the EQ-5D-5L and EQ VAS will be used

The EQ-5D-5L is a generic instrument, designed for self-completion, to describe and value health. It is based on a descriptive system that defines health in terms of 5 dimensions: Mobility, Self-Care, Usual Activities, Pain/Discomfort and Anxiety/Depression. Each dimension has 5 response categories corresponding to no problems, slight problems, moderate problems, severe problems and extreme problems.

Study description

Background summary

According to the World Health Organisation (WHO) every year 28% to 35% of the elderly population (>65 years) falls and this number increases as age rises.

Fall incidents can lead to injuries, handicaps and in some cases to death. In 40% to 60% fall incidents result in injuries and 5% of the injuries are fractures. This increase in morbidity leads to more hospital admissions. A large retrospective study conducted in the Netherlands assessed trends in falls mortality in Dutch persons 80 years and older from 2000 through 2016. They discovered a tremendous increase in total number of lethal falls from 391 deaths in 2000 to 2501 deaths in 2016.

The incidence of dizziness in the elderly population varies from 20% to 30%, and with every five years increase in age there is a 10% higher chance of an elderly person suffering from dizziness. Recently, Vieira et al. wrote an article about common risk factors of fall incidents and about possible methods to prevent old people from falling. One of the discussed risk factors is a balance disorder. However, vestibular disturbances, such as benign paroxysmal positional vertigo (BPPV), as potential reasons for fall incidents were not discussed. This is a limitation because a considerable number of elderly people suffer from BPPV, and BPPV may cause fall incidents. Furthermore, BPPV is easy to treat.

Since it has been proven that elderly people with complaints of dizziness experience a lower quality of life, ideally BPPV should be treated at all times. Repositioning manoeuvres, like the Epley or Semont manoeuvre in case of a posterior BPPV or the Lempert manoeuvre in case of a horizontal BPPV, are effective and safe conservative treatments. People who suffer from posterior BPPV can be successfully treated with a single manoeuvre in 85% of the cases. Retrospective studies demonstrated a decrease in the number of fall incidents in older people after successful treatment of BPPV. However, the risk of recurrence after successful treatment appears to be higher in older people10 and in patients with anxiety and/or depression symptoms.

Studies conducted so far demonstrate various prevalences of BPPV in the elderly. Oghalai et al. recorded the presence of dizziness in the elderly population using a questionnaire. They found a prevalence of unrecognised BPPV in 9% of the study population, accompanied with a higher occurrence of fall incidents. Another study showed BPPV in 1.4% of elderly patients with complaints of dizziness. However, by asking patients whether they suffered from dizziness typical for BPPV, a selection was made in advance. It is known that older people can have BPPV without the typical symptoms, making the former study probably an underrepresentation of the true prevalence of BPPV in the elderly population.

Abbott et al. studied patients >65 years of age who had been admitted to the hospital because of a fall incident. Forty-five percent of this study population was diagnosed with BPPV. Though, the studied group was very small, only patients who were admitted to the hospital were included in this study and determination of a *positive Dix-Hallpike manoeuvre* was not described. Lawson et al. specifically analysed older patients of a specialised fall clinic and they found BPPV in 13% of the patients. As the amount of research regarding prevalence of BPPV and possible related fall incidents in older patients in a falls clinic is scarce, more research is needed to investigate these parameters.

The aim of our study is to determine the prevalence of BPPV in the elderly population, referred to the geriatric department with an increased risk for falling. Secondary, we aim to examine whether there is a reduction of the number of fall incidents and the severity of fall incidents after a successful repositioning manoeuvre.

Study objective

To determine the prevalence of BPPV in the elderly patients with an increased risk of falls

Secondary Objectives
To compare the outcomes within BPPV patients before and after successful treatment with a canalith repositioning manoeuvre (CRM):
* The number of fall incidents
* The severity of fall incidents
* The level of anxiety and/or depression
* The quality of life

To compare the outcomes between patients with BPPV (and subsequent treatment) and patients without BPPV:
* The number of fall incidents
* The severity of fall incidents
* The level of anxiety and/or depression
* The quality of life

We will evaluate the effect of anxiety and/or depression and quality of life on the recurrence rate of BPPV and on the number of CRM*s needed in patients treated for BPPV.

Study design

The BELFIN trial is designed as a single-centre, pre-post screening study. All eligible subjects will receive questionnaires and will undergo a diagnostic manoeuvre to determine whether they suffer from BPPV. For a more detailed explanation, see the flowchart in Chapter 3 of the Protocol.
During a period of 24 months subjects will be observed. The total research period will be 30 months.

Setting
A collaboration between the tertiary care center for dizziness, the Apeldoorn Dizziness Center (ADC) and the specialised falls clinic (Centre of Excellence for Old Age Medicine) (See Appendix 14.1), both located in Gelre Hospital Apeldoorn.

Intervention

Subjects eligible for the study will undergo a diagnostic manoeuvre (Dix-Hallpike or Supine Roll manoeuvre) to test for benign paroxysmal positional vertigo. In case the diagnostic manoeuvre shows BPPV, subjects will undergo a canalith repositioning manoeuvre (Epley, Semont, Lempert or Gufoni).

Study burden and risks

It is suggested in multiple clinical studies that canalith repositioning manoeuvres have good outcomes in the treatment of BPPV. Randomised double-blind studies demonstrated a canalith repositioning manoeuvre to be superior to sham manoeuvres in the treatment of BPPV. A Cochrane Review conducted by Hilton and Pinder in 2014 stated that the Epley manoeuvre is an effective and safe remedy for posterior canal BPPV. This was based on the results of eleven randomised controlled trials.
Severe complications from canalith repositioning manoeuvres have not been reported in randomised controlled trials. The guidelines of the Dutch College of General Practitioners advise to perform an Epley manoeuvre in case of BPPV. According to the Clinical Practice Guideline of the American Academy of Otorhinolaryngology * Head and Neck Surgery Foundation CRM*s are associated with mild and mostly self-limiting adverse effects such as a sensation of falling, nausea, vomiting, fainting and conversion to lateral canal BPPV. Conversion from posterior to lateral canal BPPV occurs in approximately 6-7%. Nausea occurs in 16.7% up to 32% during a repositioning manoeuvre.

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

Adult patients, understanding of the Dutch language, aged 65 years or older, referred to the geriatrics with an increased risk for falling according to the Fall-Risk Questionnaire (FRQ)

Exclusion criteria

Active additional neuro-otologic disorders that may mimic BPPV (e.g. vestibular migraine, recurrent vestibulopathy, Ménière*s disease, vertebro-basilair TIAs, acoustic neuroma), severe disability (e.g. neurological, orthopedic, cardiovascular) or serious concurrent illness that might interfere with diagnostic or repositioning manoeuvres.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-11-2018

Enrollment:	288
Type:	Actual

Ethics review

Approved WMO Date:	28-09-2018
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	NL65860.058.18