Characterization of Bilateral Vestibulopathy

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1. Investigate health care consumption of patients with bilateral vestibulopathy2. Investigate patient expectations of the vestibular implant3. Define inclusion criteria for vestibular implantation4. Define diagnostic approach for patients with...

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

Summary

ID

NL-OMON47391

Source
ToetsingOnline

Brief title
Characterization of Bilateral Vestibulopathy

Condition

- Inner ear and VIIIth cranial nerve disorders

Synonym
Total loss of balance function; Total vestibular areflexia

Research involving
Human

Sponsors and support

Primary sponsor: Med-El
Source(s) of monetary or material Support: Bedrijf: Med-El

Intervention

Keyword: bilateral areflexia, bilateral vestibulopathy, characterization, health care consumption

Outcome measures

Primary outcome

1. A detailed overview of the health care consumption of patients with

bilateral vestibulopathy

2. A detailed insight in the patient expectations of the vestibular implant

3. Defined strict inclusion criteria for vestibular implantation

4. A defined diagnostic approach for patients with bilateral vestibulopathy

Secondary outcome

not applicable

Study description

Background summary

Bilateral vestibular loss (BV) represents a major handicap with strong balance disturbances, higher risk of fall, visual symptoms (oscillopsia) and a loss of autonomy.
Prognosis is poor and treatment options are limited. At this moment, the department of ORL of Maastricht University Medical Center is working on a vestibular implant. Aim is to (partially) restore vestibular function.
However literature about the costs and burden of BV are scarce. Moreover, there is no consensus regarding vestibular testing procedures and the characteristics that define BV. These are all important parameters for the implementation of the vestibular implant as a regular therapeutic device.

Study objective

1. Investigate health care consumption of patients with bilateral vestibulopathy
2. Investigate patient expectations of the vestibular implant
3. Define inclusion criteria for vestibular implantation

4. Define diagnostic approach for patients with bilateral vestibulopathy

Study design

Observational Study

Study burden and risks

After returning written informed consent, selected patients will undergo:
- Detailed interview (about 1 hour). No burden is expected for the patients, except time. One could hypothesize a psychological burden since patients will be interviewed about their past psychological/psychiatric history. However, this issue has already been addressed during their previous regular visits (when the diagnosis was made). Until now, no patients have refused or felt uncomfortable to inform us about their past medical history. If so, these patients will be excluded and not invited for the study.
- An extensive physical, audiometric and vestibular examination (about 3 hours), which are routinely performed at our ENT-department, to investigate patients with balance disorders. Due to the nature of their disease (bilateral vestibulopathy), these patients will not get sick by these tests, compared to persons with a still (partially) intact vestibular function.
All tests can be performed at one day. The major burden for the patient is time: one day is spent at our department in Maastricht.

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

- Bilateral vestibulopathy, diagnosed at Maastricht University Medical Center
- >18 years old
- Giving informed consent

Exclusion criteria

- Not being able (e.g. mentally disabled) or willing to talk about one of the investigated issues (e.g. psychology/psychiatry, health care utilization
- Not being able or willing to undergo one of the detailed physical, audiometric or vestibular examinations.
- Incapacitated patients

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	22-06-2016

Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	17-06-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20731
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL52768.068.15
OMON	NL-OMON20731

Study results

Date completed: 30-07-2018

Summary results
Trial ended prematurely