Characterization of Bilateral Vestibulopathy II

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1. Define diagnostic approach for patients with bilateral vestibulopathy.2. Define inclusion criteria for vestibular implantation.3. Investigate patient expectations of the vestibular implant. 4. To gain a clear insight into consumption of health...

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

Summary

ID

NL-OMON49984

Source
ToetsingOnline

Brief title
Characterization of Bilateral Vestibulopathy II

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: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Bedrijf: Med-El

Intervention

Keyword: bilateral areflexia, Bilateral vestibulopathy, characterization

Outcome measures

Primary outcome

1. A defined diagnostic approach for patients with bilateral vestibulopathy.

2. Defined strict inclusion criteria for vestibular implantation

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

4. A detailed insight into consumption of health care by patients with

bilateral vestibulopathy

Secondary outcome

Not applicable

Study description

Background summary

Bilateral vestibulopathy (BV) represents a major handicap with strong balance disturbances, higher risk of fall, visual symptoms (oscillopsia) and 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 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. Define diagnostic approach for patients with bilateral vestibulopathy.
2. Define inclusion criteria for vestibular implantation.
3. Investigate patient expectations of the vestibular implant.
4. To gain a clear insight into consumption of health care by patients with

bilateral vestibulopathy.

Study design

Observational study

Study burden and risks

After returning written informed consent, selected patients will undergo:
- Detailed interview (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 visits (when 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 4 hours), which are routinely perfermed 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. One week before visiting the ENT department, the patient wil wear a motion sensor. This is al very small en light device en will have no burden for the patient. All test 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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- Bilateral vestibulopathy, diagnosed at Maastricht University Medical Center according to the Bárány criteria:
* Horizontal angular VOR gain bilaterally <0.6
* And/or sum of the maximal peak velocities of the slow phase caloric induced nystagmus (stimulation with warm and cold water) bilaterally <6°/s
* And/or VOR gain <0.1 upon sinusoidal stimulation on torsion swing test (and/or a phase lead >68 degrees on torsion swing test)
- >18 years old
- Giving informed consent

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- 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.
- Not being able to stop medication against anxiety or depression (after consulting their general practitioner)
- Not wanting to be informed about any incidental findings

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-08-2021
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	29-04-2020
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: 21431
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL72200.068.19
OMON	NL-OMON21431