

# 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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Inner ear and VIIIth cranial nerve disorders
<b>Study type</b>	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 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. One week before visiting the ENT department, the patient will wear a motion sensor. This is a very small and light device and will have no burden for the patient. 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**

### **Public**

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### **Scientific**

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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  $<6^{\circ}/s$
  - \* 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: NTR

Title:

## In other registers

Register	ID
CCMO	NL72200.068.19
OMON	NL-OMON21431