Characterization of bilateral vestibulopathy

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20731

Source
NTR

Health condition

Bilateral vestibulopathy

Sponsors and support

Primary sponsor: Academisch Ziekenhuis Maastricht
Source(s) of monetary or material Support: Med-El

Intervention

Outcome measures

Primary outcome

- Detailed insight into consumption of health care by patients with bilateral vestibulopathy

- A detailed insight into the patient expectations of the vestibular implant

- Defined strict inclusion criteria for vestibular implantation

- A defined diagnostic approach for patients with bilateral vestibulopathy

Secondary outcome

Not applicable

Study description

Background summary

Rationale:

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.

Objectives:
1. To gain a clear insight into consumption of health care by patients with bilateral vestibulopathy in Europe

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 population: Sixty adult patients previously diagnosed with bilateral vestibulopathy at our vestibular department

Intervention:
Patients will be invited for one day to our outpatient department for:

- A detailed interview about several topics: costs related to their disease, course of disease, co-morbidity and medication, previous psychological/psychiatric help and standardized questionnaires about quality of life, loss of productivity, anxiety and depression and vestibular complaints

- Detailed physical, audiometric and vestibular examinations, as routinely performed at our department

- Imaging and blood work as routinely performed for this disease (if not yet available), as part of regular care.

Main study parameters/endpoints:
1. A detailed insight into consumption of health care by 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

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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.

- Imaging and blood work, only if not yet performed as a part of the regular care. Imaging will involve an MRI-scan of the brain/cerebellopontine angle and will take approximately 45 minutes. Patients who are claustrophobic do not have to undergo this scan and will not be excluded. Blood work involves ANA/ANCA, vitamins, folate, TSH/fT4, Hba1C, Borrelia and Lues serology. The expected burden is a potentially painful needle when taking the blood samples.

- Some of the medications have to be stopped for the vestibular examination. The

medications that have to be stopped are all the medicines against anxiety (e.g. SSRI's, benzodiazepines) or depression. Patients are only allowed to stop their medication after consulting their doctor. If they are not able to stop, they will be excluded from the study. Stopping these medications is a standard demand in our hospital for each patient that will undergo vestibular testing. Until now, we have not experienced any problems with patients who stopped their psychiatric medication for a short period of time.

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.

Study design

1 day

Intervention

After obtaining a candidate's written informed consent, the patient will receive the questionnaires by mail and be invited for investigations at our outpatient department. On the day of the investigations, the main investigator will check the form one more time together with the patient.

The investigations comprise:

1. Detailed Interview:

- Determine course of disease (differentiatie e.g. migraine, Meniere's, Meniere-like, Recurrent vestibulopathy, sudden onset, etc.)

- Determine co-morbidity and medication

- Determine family-history

- Determine patient expectations

- Determine previous psychological/psychiatric help

- Standardized questionnaires vestibular: DHI, HADS, Oscillopsia

- Standardized questionnaire Quality of life : EQ-5D

- Standardized questionnaire Loss of productivity : Prodisq

- Costs-related interview (including disability, job opportunities, medical pathway before diagnosis, etc.) with a custom-made questionnaire about costs, regarding :

• Global consumption of regular and non-regular health care

• Consumption of diagnostics

• Consumption of treatments

2. Physical examination:

- ENT

- Neurological tests: oculomotor, coordination, sensibility

3. Audiometric testing:

- Audiometry: tone and speech

4. Vestibular examination:

- Electronystagmography:

• Oculomotor tests

• Torsion swing at 0.11Hz

• Calorics

- o-Vemp, c-Vemp

- video-HIT (including “magnetic scleral search coils”)

- Dynamic Visual Acuity

5. Imaging:

- If not yet available: MRI

6. Blood work, as part of regular care:

- If not yet available: ANA/ANCA, Borrelia, Treponema, vit-B1/B12, folate, glucose/HbA1c, TSH/fT4

At the end of the day, when all tests have been performed, the patient is able to go home. This is at the same time the end of his/her participation in the study.

Contacts

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Eligibility criteria

Inclusion criteria

o Bilateral vestibulopathy, diagnosed at Maastricht University Medical Center

o >18 years old

o Giving informed consent

Exclusion criteria

o Not being able (e.g. mentally disabled) or willing to talk about one of the investigated issues (e.g. psychology/psychiatry, health care utilization)

o Not being able or willing to undergo one of the detailed physical, audiometric or vestibular examinations.

o Incapacitated patients

o Not being able to stop medication against anxiety or depression (after consulting their general practitioner)

o Not wanting to be informed about any incidental findings

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2016
Enrollment:	60
Type:	Actual

Ethics review

Positive opinion

Date:	27-11-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47391
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5446
NTR-old	NTR5573
CCMO	NL52768.068.15
OMON	NL-OMON47391

Study results