VertiGO! - Get up and GO! with the vestibular implant

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The primary objective of the VertiGO! trial is to assess the feasibility of restoring vestibular function by making use of prolonged VI stimulation. This will be done using a combined VI and CI device: The CVI. To achieve this objective, patients...

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

Summary

ID

NL-OMON52541

Source
ToetsingOnline

Brief title
VertiGO!

Condition

- Inner ear and VIIIth cranial nerve disorders

Synonym
balance disorder, Bilateral vestibulopathy

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Health Holland,MED-EL,MED-EL;Stichting Heinsius Houbolt fonds

Intervention

Keyword: Balance disorder, Bilateral vestibulopathy, Vestibular implant

Outcome measures

Primary outcome

The primary objective is assessing the efficacy of the CVI in restoring vestibular function. This will be measured by using a set of vestibular tests, of which DVA will be the main outcome parameter. The tests that will be performed observe two vestibular-related reflex pathways: VOR (gaze stabilization) and VSR (postural balance). The VOR tests consist of the DVA test, the functional head impulse test (fHIT), the 3D video head impulse test (3D HIT) and the torsion swing test. All these tests quantify the VOR at different frequencies and at different levels of functionality. The VSR is observed based gait and balance tests, looking at the full body response to vestibular stimulation on a functional level. Besides these tests, also the threshold of the perception of movement will be measured using the perception platform.

The functionality of the CI-part of the CVI will be assessed with an aided consonant-nucleus-consonant (CNC) hearing test. During the CI follow-up visits speech in noise (SPIN) tests will be performed as part of the auditory follow-up test battery to allow for evaluation of the CI part of the CVI implant and compare this outcome with CI performance of a regular CI implant.

Secondary outcome

The patients subjective experience with the CVI will be quantified using both questionnaires and a number of semi-structured interviews at different points

during the study duration. An overview of the time points at which questionnaires and interviews will be administered can be found in table 1, 2, 3 and 4 of the research protocol.

The results of these questionnaires and interviews will allow us to more extensively describe our patient population, quantify the impact that both the CI and the VI functionality have on patient well-being, characterize the perceived benefit the CVI will pose to the patient and allow us to see if the CVI meets the patients* expectations. All this data will also be vital for creating a health technology assessment (HTA), which will aid the further development of the concept of vestibular stimulation.

Study description

Background summary

The vestibular sensory organ is essential for balance and image stabilization. It drives the eyes to keep the image of the environment stable. Severe function loss of both vestibular organs is referred to as bilateral vestibulopathy (BV). Patients with BV present themselves with serious day-to-day disabilities such as strong balance disturbances, higher risk of falling, visual symptoms (oscillopsia) and a loss of autonomy. It has been conservatively estimated that more than 200.000 people in Europe and 2.1 million people worldwide are affected. Up until now no effective treatment is available for these patients. In the past years experimental electric stimulation of the vestibular nerve in humans by means of a vestibular implant (VI) has shown to be able to partly restore balance and gaze functionality in test situations. After showing feasibility of vestibular stimulation in humans in previous trials (NL36777.068.11, NL31405.068.10), the current step in this trial will be to show that prolonged daily stimulation is effective and safe.

Study objective

The primary objective of the VertiGO! trial is to assess the feasibility of restoring vestibular function by making use of prolonged VI stimulation. This will be done using a combined VI and CI device: The CVI. To achieve this

objective, patients will use the wearable CVI device during three weeks within the safety of a hospital environment. This trial will serve as a proof-of-concept for restoring functional, long-term vestibular function to patients with BV, an as-of-yet untreatable disorder causing severe impairment and discomfort. The aims of this trial are to investigate efficacy and safety of prolonged vestibular stimulation, to identify the influence of different stimulation algorithms, to assess the feasibility of the combined VI/CI device, and to further build on the fundamental knowledge of vestibular organ stimulation while also taking into account the patient perspective.

1. Primary
a. To investigate the efficacy of prolonged daily VI stimulation
b. To investigate the safety of prolonged daily VI stimulation
c. To investigate the efficacy of three different types of stimulation: baseline stimulation without motion modulation, baseline stimulation with motion modulation, reduced baseline stimulation with motion modulation

2. Secondary
a. To develop a rehabilitation program for VI recipients
b. To evaluate the interaction between vestibular and cochlear nerve stimulation
c. To evaluate acute VI performance across several years

Study design

Controlled clinical trial with a randomized single-blind cross-over design

Intervention

To evaluate combined prolonged stimulation of both the vestibular organ and the cochlea, subjects will be implanted with the cochlear-vestibular implant (CVI). This extended CI also incorporates a vestibular component (VI) in order to restore both hearing and vestibular function. Once the prosthesis is implanted, the patient will pay scheduled visits to our clinic. Hearing rehabilitation with the CI will follow the standard clinical protocol. Evaluation of the VI functionality will include a CBCT scan 1 week post-op, 1 hour extra testing at the end of the CI rehabilitation period, a VI fitting period (4 days), a day of baseline testing, 3 periods of 4 days prolonged VI stimulation and tests conducted during regular CI follow-up visits until 5 years after implantation, including 3 CBCT scans (12 hours extra during standard visits). An overview of the trial schedule is given in figure 1 of the reasearch protocol. More detailed overviews can be found in chapter 3 of the research protocol. During the fitting period and the prolonged stimulation period the patients will be staying in a hotel next to the hospital. During the prolonged stimulation period, subjects will follow a vestibular rehabilitation program and the outcomes will be evaluated using a set of vestibular tests (including video-oculography (VOG), perception tests and test of gait), auditory tests,

semi-structured qualitative interviews and questionnaires.

Study burden and risks

The main burden associated with participation is significant time investment. Patients will undergo both CI inclusion testing (2 visits) and VI inclusion testing (1 visit) and be admitted for surgery (2 days). After surgery, patients will visit the hospital for the regular CI visits and for trial-specific visits. The trial specific visits include a VI fitting period (4 days), baseline testing (1 day) and the prolonged stimulation period (3*4 days). During a number of the regular CI visits extra tests will be conducted specifically for the trial (see table 1, chapter 4 of the research protocol). During the fitting period and the prolonged stimulation period, patients will be staying in a hotel next to the hospital to reduce the burden of travel on the patients. During the visits, rehabilitation exercises, vestibular tests, hearing tests and interviews will be executed. All of these activities are associated with a low physical and psychological burden. Personal limits of patients will explicitly be taken into account.
The most substantial risks involved with receiving a CVI is damage to the neural structures within the cochlea and the vestibular system. Therefore, we apply stringent inclusion criteria and will only implant patients with disabling symptoms of BV and severe SNHL in the ear to be implanted, to minimize the amount of potential damage that can be done. Alongside this, outside of the research setting, the CVI implant will function as a regular CI, restoring hearing in the ear to be implanted and compensating for the loss in natural hearing potentially occurring by inserting the electrodes into the inner ear. Other risks associated with implantation of the CVI are estimated to be minimal based on previous CVI implantations performed in our clinic (NL36777.068.11, NL31405.068.10) and similar to risks associated with implanting and using a regular CI.
Risks of vestibular stimulation via the CVI include dizziness, nausea and a risk of falling. The risks of dizziness and nausea will most likely subside as the patient gets more used to vestibular stimulation, and can always be negated by stopping the vestibular stimulation. The risk of falling, alongside any unforeseen risks, are minimalized by taking care and time to let the patient get used to vestibular stimulation and by only applying vestibular stimulation while the patient is in the hospital under supervision by a member of the research team. While the patient receives vestibular stimulation via the CVI, the performance of the CI-part of the implant might be reduced.
The benefit for the patient is that via the CI functionality of the CVI their hearing will most likely improve, analogous to a regular CI. The VI functionality of the CVI can only be used within a research setting, and will therefore not result in a direct patient benefit outside off trial related activities under supervision in the hospital.
Concerning group relatedness, BV represents a major handicap with strong balance disturbances, higher risk of falling, visual symptoms (oscillopsia) and a loss of autonomy. There is no therapeutic strategy at the moment.

Development of a vestibular prosthesis could help this group of patients to have a better quality of life. With this study we hope to answer crucial research questions (see chapter 1.4 of the research protocol) and bring essential knowledge towards the development and refining of a vestibular prosthesis. This trial is part of a larger plan to develop the concept of a VI which can be adopted into clinics. As described in chapter 1.4, substantial research has been conducted with VI stimulation in the past. This trial serves as the next step in this process. If this trial succeeds in proving the safety and efficacy of prolonged vestibular stimulation, future trials with a larger patient cohort are in the pipeline to build on the knowledge gathered in this trial.

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

- Disabling symptoms of bilateral vestibulopathy
- Severe sensorineural hearing loss in the ear to be implanted
A full list of the inclusion criteria can be found in chapter 4.2 of the research protocol

Exclusion criteria

- Clear signs of structural nerve pathology or indications of improperly functioning vestibular nerves
- Orthopedic, ocular, neurologic or other non-vestibular pathologic conditions of sufficient severity to confound vestibular function tests used in the study
A full list of the exclusion criteria can be found in chapter 4.3 of the research protocol

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2021
Enrollment:	13
Type:	Actual

Medical products/devices used

Generic name:	Cochlear-Vestibular implant (CVI)
Registration:	No

Ethics review

Approved WMO Date:	06-04-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	15-08-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	28-11-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	17-12-2024
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT04918745
CCMO	NL73492.068.20