Implantation of a vestibular prosthesis.

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1. By implanting a vestibular prosthesis which provides sufficient electrical stimulation of the ampullary nerves, a congruent vestibulo-ocular reflex (VOR) will occur; 2. The parameters of the VOR can be modified by adjusting the settings of the...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22853

Bron
Nationaal Trial Register

Verkorte titel
VI

Aandoening

cochlear implant, vestibular implant, vestibular prosthesis, bilateral vestibular areflexia, cochleair implant, vestibulair implantaat, vestibulaire prothese, bilateraal vestibulair functieverlies

Ondersteuning

Primaire sponsor: Maastricht University Medical Centre (MUMC+)
Overige ondersteuning: Maastricht University Medical Centre (MUMC+)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. The gain, phase and direction of VOR will be measured and adjusted accordingly, with use of electronystagmography and video-nystagmography in function of frequency and amplitude

of electric stimulation in the conditions mentioned below:
A. Patients with different vestibular loss etiology;
B. Stimulation of the superior, lateral and posterior ampullary nerve;
C. Using a long-term implanted vestibular prosthesis.
2. Performance in balance tests (routine ENG-examination);
3. Questionnaires about subjective parameters;
4. Audiometric results pre- and postoperatively (including audiometric results during activation of the implant).

Toelichting onderzoek

Achtergrond van het onderzoek

A vestibular prosthesis will be implanted and adjusted, until desired responses from the vestibular system are obtained. This is a main step in developing the vestibular implant.

Doel van het onderzoek

1. By implanting a vestibular prosthesis which provides sufficient electrical stimulation of the ampullary nerves, a congruent vestibulo-ocular reflex (VOR) will occur;

2. The parameters of the VOR can be modified by adjusting the settings of the vestibular implant;

3. Using the vestibular implant will lead to improvement of objective and subjective vestibular parameters.

Onderzoeksopzet

After vestibular examinations pre-operatively, implantation and follow-up will take one year.

Onderzoeksproduct en/of interventie

1. To implant a functional vestibular prosthesis using the ampullar “V”-approach, as developed in our own clinic.

2. To investigate protocols for adjusting the vestibular implant (VI) to required settings, regarding:

A. Modulation sensitivity;

B. Baseline firing rate and current;

C. VOR-axis, using precompensation.

3. To investigate the benefit of the vestibular implant regarding:

A. Objective parameters (balance test results);

B. Subjective parameters (quality of life, etc.).

4. To investigate interference with hearing during vestibular stimulation;

5. To investigate adaptation of the brain to the vestibular implant.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Since vestibular surgery still has a risk of deafening the patients, the selected patients are >18 years old, have a bilateral loss of vestibular function with disabling symptoms and have a severe perceptive hearing loss in at least one ear (in other words: they are already deaf in the tested ear);

2. Giving informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Incapacitated patients;

2. Carrier of any other implanted electronic device (e.g. pace-maker);

3. Contra-indication for general anesthesia.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-07-2011
Aantal proefpersonen:	5
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 41428
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2751
NTR-old	NTR2890
CCMO	NL36777.068.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON41428

Resultaten

Samenvatting resultaten
N/A