Electric stimulation of the ampullary nerves.

Gepubliceerd: 01-05-2010 Laatst bijgewerkt: 18-08-2022

By sufficient electrical stimulation of the ampullary nerves, a congruent vestibulo-ocular reflex will occur.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26569

Bron
NTR

Verkorte titel
ESAN

Aandoening

Vestibular prosthesis
Vestibulaire prothese
Vestibular implant
Vestibulair implantaat
Bilateral vestibular loss
Bilateraal vestibulair functieverlies
Cochlear implant
Cochleair implantaat

Ondersteuning

Primaire sponsor: Maastricht University Medical Centre
Overige ondersteuning: Maastricht University Medical Centre

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The gain, phase and direction of VOR will be measured with electronystagmography and video-nystagmography in function of frequency and amplitude of electric stimulation in the conditions mentioned below:
1. Patients with different vestibular loss etiology;
2. Stimulation of the lateral ampullary nerve and posterior ampullary nerve;
3. Under general and local anesthesia.

Toelichting onderzoek

Achtergrond van het onderzoek

We try to determine the best stimulation profile and surgical technique which lead to an optimal response (congruent vestibulo-ocular reflex) when stimulating the ampullary nerve. This is a main step in developing the vestibular implant.

Doel van het onderzoek

By sufficient electrical stimulation of the ampullary nerves, a congruent vestibulo-ocular reflex will occur.

Onderzoeksopzet

Apart from extra vestibular tests and questionnaires in order to confirm the bilateral vestibular loss and disability, the procedure during cochlear surgery is the only intervention where all the data is collected.

Onderzoeksproduct en/of interventie

The intervention only takes 20 minutes and is performed during surgery for cochlear implantation.

The beginning of the procedure will be done under local anesthesia. The posterior ampullary nerve and the lateral ampullary nerves (parts of the vestibular nerve) will be exposed with the approache described by Guyot et al. The electric stimulation of the nerve will be done following the established profile (pulsatile stimulation, different stimuli patterns), eyes movement will be registered with electronystagmography and video-nystagmography (routinely used). Then general anesthesia will be induced. A last electric stimulation following the established profile will be done. Then cochlear implantation will be performed as usual.

There is no control group.

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 and are selected for cochlear implant surgery (in other words: they are already deaf);

2. Giving informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients should be able to undergo balance tests and electric stimulation of the ampullary nerves should not interfere with other electric devises. Therefore, the exclusion criteria are:

1. Incapacitated patients;

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

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:	01-06-2010
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	01-05-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2185
NTR-old	NTR2310
CCMO	NL31405.068.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A