Electric stimulation of the ampullary nerves.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26569

Source
NTR

Brief title
ESAN

Health condition

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

Sponsors and support

Primary sponsor: Maastricht University Medical Centre
Source(s) of monetary or material Support: Maastricht University Medical Centre

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Assessment of the subjective feelings during stimulaton of the ampullary nerves in local anesthesia, like vertigo or nausea.

Study description

Background summary

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.

Study objective

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

Study design

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.

Intervention

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.

Contacts

Public
Postbus 5800
Raymond Berg, van de
Maastricht 6202 AZ
The Netherlands
+31 (0)43 3875400
Scientific
Postbus 5800
Raymond Berg, van de
Maastricht 6202 AZ
The Netherlands
+31 (0)43 3875400

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2010
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	01-05-2010
Application type:	First submission

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

Study results

Summary results
N/A