Intracochlear position and cochlear implant outcomes using the Nucleus Slim Modiolar Electrode and the (extended) round window approach: a follow up study

Gepubliceerd: 15-01-2020 Laatst bijgewerkt: 18-08-2022

Previously published research by Heutink et al. performed in our center found cochleostomy associated translocations in over a third of the patients implanted with the Slim Modiolar Electrode. Therefore, we would like to evaluate the translocation…

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23746

Bron
NTR

Verkorte titel
SME/RW

Aandoening

- Severe-to-profound sensorineural hearing loss
- Cochlear implantation
- Electrode tip foldover
- Residual hearing loss

Ondersteuning

Primaire sponsor: Cochlear Ltd. Benelux
Overige ondersteuning: Cochlear Benelux Ltd.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Occurrence of intraoperative tip fold-over and evaluation of the intracochlear position of electrode contacts (ST or SV) per participant

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Due to the continuingly expanding indications for cochlear implantation, preservation of residual hearing has become an important objective. Evidence suggests that overall outcome and hearing preservation are influenced directly by occurrence of insertional trauma (i.e. lateral wall/modiolar trauma, translocation from scala tympani to scala vestibuli, tip fold-over) during surgery. Therefore there is an increasing interest in hypotraumatic insertion techniques as well as hypotraumatic electrode arrays. The Slim Modiolar Electrode (SME) was developed in 2016 to be atraumatic, more flexible and thinner than previous generations of precurved electrode arrays by the manufacturer. Heutink et al. confirmed the potential for the SME to preserve residual hearing once the electrode was positioned entirely in the scala tympani (ST). However, they observed cochleostomy associated translocation to the scala vestibuli (SV) in more than one third of the participants, resulting in significant hearing loss. They therefore advise to use the round window (RW) or extended round window ((e)RW) approach when using the SME.

Objective:
To evaluate the intracochlear position of the Slim Modiolar Electrode array when inserting using the (e)RW approach.

Study design:
Prospective observational study

Study population:
The first 23 patients selected for implantation with the Slim Modiolar Electrode (CI532/CI632) using the (extended) round window approach at our center willing to participate.

Follow-up:
1 year.

Primary outcome measure:
Occurrence of intraoperative tip fold-over and evaluation of the intracochlear position of

electrode contacts (ST or SV) per participant.

Secondary outcome measures:
Residual hearing thresholds and speech perception in relation to intracochlear location of electrode contacts per participant.

Doel van het onderzoek

Previously published research by Heutink et al. performed in our center found cochleostomy associated translocations in over a third of the patients implanted with the Slim Modiolar Electrode. Therefore, we would like to evaluate the translocation rate in a similar group of patients implanted with the SME using the (extended) round window approach. We expect to find a lower rate of electrode translocation in patients using this surgical technique.

Onderzoeksopzet

1. <6 months prior to surgery
2. 2 months
3. 1 year

Onderzoeksproduct en/of interventie

-

Contactpersonen

Publiek

Radboudumc
Tim Klabbers

0243614933

Wetenschappelijk

Radboudumc
Tim Klabbers

0243614933

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Patients selected for cochlear implantation with the Slim Modiolar Electrode (Cochlear Ltd.) in the Radboudumc who are willing to participate and have signed informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Contraindications for CT-scanning
2. Patients with anatomical variations of the cochlea that may influence normal insertion (this is judged on the pre-operative CT-scan)
3. Children (< 18 years)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2019
Aantal proefpersonen:	23
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL8290
Ander register	CMO Radboudumc : 2019-5821

Resultaten