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

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23746

Source
NTR

Brief title
SME/RW

Health condition

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

Sponsors and support

Primary sponsor: Cochlear Ltd. Benelux
Source(s) of monetary or material Support: Cochlear Benelux Ltd.

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Residual hearing thresholds and speech perception in relation to intracochlear location of electrode contacts per participant.
2. Compare audiometric outcome and translocation rate between surgical techniques (RW vs CS).

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

-

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2019
Enrollment:	23
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable
Application type: Not applicable

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	NL8290
Other	CMO Radboudumc : 2019-5821

Study results