The value of trans-impedance matrix (TIM) measurements for detecting new bone formation (NBF) and influence on electrophysiology, residual hearing and performance

Gepubliceerd: 25-11-2019 Laatst bijgewerkt: 15-05-2024

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26583

Bron
NTR

Verkorte titel
TIM and NBF

Aandoening

- severe-to-profound sensorineural hearing loss
- cochlear implantation
- trans-impedance matrix (TIM) measurement
- residual hearing loss
- new bone formation (NBF)

Ondersteuning

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

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Predictive value of TIM for detecting NBF in CI patients.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Cochlear implantation (CI) can result in post-operative intracochlear changes such as the formation of connective tissue and even new bone formation. This has been observed to lead to higher impedances, subsequent higher energy consumption and out-of-compliance issues. It may also influence long term residual hearing, lead to channel interaction and impact performance directly. Trans-impedance matrix (TIM) measurement is a promising non-invasive and simple technique which could possibly be used as a clinical diagnostic tool for NBF in the future.

Objective:
Determine the value of prospective TIM-measurement for the detection of NBF in patients after cochlear implantation by comparing to ultra-high resolution (UHR) CT imaging and determine the clinical relevance of NBF by studying the relationship between NBF and electrophysiological parameters, residual hearing and speech perception development.

Study design:
Prospective pilot study

Study population:
30 patients selected for cochlear implantation at the Radboudumc with Cochlear Ltd. electrodes (Nucleus Slim Straight, Nucleus Contour Advance and Nucleus Slim Modiolar electrode) without contraindications for CT-scan or an anatomical situation that may influence normal insertion of the CI.

Intervention:
Intra- and post-operative TIM measurement and pre- and postoperative UHR CT-scan of the petrosal bone

Follow-up:
1 year including (standard) scheduled follow-up visits at 1, 2, 4, 6, 8 weeks and at 3, 6 and 12 months.

Primary outcome measure:
Predictive value of TIM-measurement for detection of NBF

Secondary outcomes measures:
Influence of NBF on residual hearing, C-T level changes in relation to NBF growth, timing of NBF formation

Data analysis:
An initial analysis at patient level will be performed in which we will evaluate the relationship between the fraction of electrode contacts with NBF per patient per timepoint with the average TIM measurement for that patient and timepoint, as well as with the increase in TIM level up to that timepoint. If possible, a ROC curve will be estimated, although the amount of data will presumably be too small for this analysis to be confirmative.
Additional analysis will also be performed to evaluated the new bone formation at electrode level, using a complex logistic regression model with NBF at individual contact level as dependent variable per timepoint and with a random effect for patient and TIM parameters as independent variables.

Doel van het onderzoek

Previous, unpublished research performed in our center showed promising results for the ability of TIM measurements to predict the presence of new bone in CI patients; higher TIM values were measured in contacts with NBF compared to those without. Therefore, we expect to find an association between an increase in TIM level over time and presence of NBF in CI patients.

Onderzoeksopzet

1. <6 months prior to surgery
2. Baseline (Implantation date)
3. 1 week
4. 2 weeks
5. 4 weeks
6. 6 weeks
7. 8 weeks
8. 3 months
9. 6 months
10. 12 months

Onderzoeksproduct en/of interventie

Trans-impedance matrix (TIM) measurement, ultra-high resolution CT-scan

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 a Cochlear Ltd. Implant in the Radboudumc

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)
4. Prelingual hearing loss

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:	06-11-2019
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	25-11-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48046
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8184
CCMO	NL70799.091.19
OMON	NL-OMON48046

Resultaten