Cochlear implant receiver/stimulator fixation with and without drilling; a randomized controlled study

Gepubliceerd: 31-08-2021 Laatst bijgewerkt: 18-08-2022

Subperiosteal tight pocket fixation technique is not inferior to the bony bed fixation technique on migration of the receiver/stimulator at 12 months.

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

Samenvatting

ID

NL-OMON28350

Bron
NTR

Verkorte titel
COMFIT

Aandoening

Sensorineural hearing loss, deafness

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: Oticon Medical

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary objective of this study is to compare the migration rates of the two fixation

techniques (bony bed vs. subperiosteal tight pocket) by analysing 3D reconstructions of the R/S device, acquired by Cone Beam CT (CBCT) scans at baseline and during follow up.

Toelichting onderzoek

Achtergrond van het onderzoek

Cochlear implantation is a surgical procedure that requires careful planning and execution. The correct electrode array placement in the cochlea is crucial for optimal functionality of the device. This array is connected to the receiver/stimulator, which is placed under the temporalis muscle, in close proximity to the ear pinna. During cochlear implant (CI) positioning, the R/S device should be placed close enough to the pinna, without possible interference of the microphone in the behind-the-ear device laying (partially) on top of the R/S device. Fixation of the device on the skull is also important because if the device migrates towards the ear, it could cause pain or discomfort to the patient and it could have an effect on the position of the electrode array in the cochlea. The latter is suggested but not proven. Surgical experts and manufacturers still reach for consensus on the correct fixation method of the R/S device, that is to say, the method that least endanger optimal CI functionality while also having the least intra- and postoperative risks.
There are currently up to eleven different fixation methods being applied in practice. In our clinic, the technique used for fixation requires drilling out a part of the bony cortex of the skull (respecting a thin medial layer without exposing dura mater), where the R/S device will be placed (the bony bed technique). Another widely used technique is fixation of the device under the periosteum and temporal muscle by creating a tight pocket (the subperiosteal tight pocket technique). This technique has the advantage of a smaller incision (less invasive operation), shorter operational time, and it eliminates risks of complications that could occur when drilling out a bony bed (such as dural damage). Creating the subperiosteal pocket might also require less manipulation of the temporalis muscle (compared to the mentioned bony bed technique), thereby minimizing the risk of postoperative hematoma even more. We conducted a literature review to compare the migration rates between these two techniques and the results were inconclusive due to a lack of methodologically high quality studies. Thus there is no quality evidence to support the superiority of either technique.
Therefore we propose to investigate the migration rates of the two fixation techniques (bony bed vs. subperiosteal tight pocket).

Doel van het onderzoek

Subperiosteal tight pocket fixation technique is not inferior to the bony bed fixation technique on migration of the receiver/stimulator at 12 months.

Onderzoeksopzet

Baseline (postoperative), 1 week, 4 weeks, 8 weeks, 3 months and 12 months after CI surgery.

Onderzoeksproduct en/of interventie

Subperiosteal tight pocket fixation technique.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• The patient has provided written informed consent authorization before participating in the study.
• The patient is ≥18 years of age at the time of consent.
• The patient is a primary cochlear implantation candidate according to all standard care criteria.
• The patient has Dutch written language proficiency.
• The patient is physically able to undergo a CBCT scan.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Revision surgery
• Re-implantation
• Inability to understand or sign informed consent

• Pregnancy during the trial

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	26-08-2021
Aantal proefpersonen:	112
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:	31-08-2021
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	NL9698
Ander register	METC UMC Utrecht : METC 21-449

Resultaten