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

No registrations found.

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

Summary

ID

NL-OMON28350

Source
NTR

Brief title
COMFIT

Health condition

Sensorineural hearing loss, deafness

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: Oticon Medical

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

• To investigate the difference in patient-experienced burden using the validated COMPASS questionnaire between the two fixation techniques.
• To compare the electrode array migration rate between the two techniques.
• To compare electrode impedance values between the two techniques and association with R/S device and electrode migration.
• To investigate whether complaints of performance drop, vertigo, tinnitus, headache or nonauditory stimulation are associated with electrode array migration and R/S device migration.
• To compare the complication rate of these surgical techniques, for major and minor complications.
• To assess the diagnostic accuracy and validate the measurement method technique with flexible tape measure for the assessment of migration of the R/S device.

Study description

Background summary

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).

Study objective

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

Study design

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

Intervention

Subperiosteal tight pocket fixation technique.

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Eligibility criteria

Inclusion criteria

• 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.

Exclusion criteria

• Revision surgery
• Re-implantation
• Inability to understand or sign informed consent
• Pregnancy during the trial

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-08-2021
Enrollment:	112
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	31-08-2021
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	NL9698
Other	METC UMC Utrecht : METC 21-449

Study results