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

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hearing disorders
Study type	Interventional

Summary

ID

NL-OMON54404

Source
ToetsingOnline

Brief title
COMFIT trial

Condition

- Hearing disorders
- Head and neck therapeutic procedures

Synonym
cochlear implant surgical techniques

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Oticon Medical

Intervention

Keyword: cochlear implant, electrode array, fixation, surgical techniques

Outcome measures

Primary outcome

Primary endpoint: Migration of the R/S device, measured in millimetres and

degrees.

Secondary outcome

Secondary endpoints:

- COMPASS questionnaire scores

- Electrode array migration

- Electrode impedance values

- Audiological results (cvc wordtest score)

- Complication rates

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.

Study objective

The primary objective of this study is to compare the migration rates of the two fixation techniques (bony bed vs. subperiosteal pocket), and assess the feasibility of the techniques, thereby assuring the stability of the implant with the least patient burden. Our secondary objective is a difference in patient-experienced burden using the validated COMPASS questionnaire

Study design

Single blind, randomized controlled trial. Patients are randomized into one of two groups, the bony bed (group A) and the subperiosteal tight pocket technique group (group B), with stratification for age (18-50 years, >50 years). Stratification is applied in both study groups.

Intervention

The R/S device of the CI will be fixated according to the respective group the patient has been allocated in. All patients will undergo a Cone Beam CT (CBCT) scan within 48 hours after surgery and at 3 and 12 months postoperatively. Patients will fill out the PROM at 3 and 12 months postoperatively.

Study burden and risks

The burden patients will experience by participating in this study will be undergoing three CBCT scans postoperatively and filling out a questionnaire twice. Patients will be scheduled to undergo these scans on the same day as a regular appointment with the audiologist of speech therapist so an extra visit

to the hospital will not be necessary. The scan exposes the patient to radiation, albeit a reduced exposure compared to a conventional CT scan.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following 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

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Revision surgery
• Re-implantation
• Other applied techniques than mentioned in the materials and methods
• Inability to understand or sign informed consent
• Pregnancy during the trial

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	27-10-2021
Enrollment:	112
Type:	Actual

Ethics review

Approved WMO Date:	26-08-2021
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	25-07-2023

Application type:	Amendment
Review commission:	METC NedMec

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
CCMO	NL76872.041.21