# Multicenter randomized controlled trial comparing surgical approaches to the cochlea for the Slim Modiolar Electrode: Assessing intracochlear trauma with intraoperative electrocochleography measurements, imaging, and residual hearing preservation.

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The aim of this study is to investigate whether the type of surgical approach to the cochlea; CO or eRW using the Nucleus 632 with the Slim Modiolar electrode affects the final residual hearing and secondarily, intracochlear trauma and electrode...

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Inner ear and VIIIth cranial nerve disorders |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON57020

**Source**
ToetsingOnline

**Brief title**
RCT comparing surgical approaches for cochlear implantation (BULLS-I)

### Condition

- Inner ear and VIIIth cranial nerve disorders

**Synonym**
cochlear implantation, Sensorineural hearing loss

**Research involving**
Human

## Sponsors and support

**Primary sponsor:** Radboud Universitair Medisch Centrum
**Source(s) of monetary or material Support:** Cochlear Ltd,Cochlear Ltd. Benelux

## Intervention

**Keyword:** Cochlear implantation, Cochleostomy, Round Window, Surgical approach

## Outcome measures

### Primary outcome

Primary outcome measure: The difference per group between pre- and postoperative (3-month) pure tone thresholds, averaged at 500, 750 and 1000 Hz (PTAlow). A difference in change of the PTAlow between approaches (CO or eRW) that exceeds 15 dB is regarded clinically significant.

### Secondary outcome

• The difference between pre- and postoperative (1 week and 12 months) pure tone thresholds, averaged at 500, 750 and 1000 Hz (PTAlow),

• Promontory ECochG threshold estimates at 500 Hz at the following stages of surgery: a) after facial recess, b) after drilling RWM overhang, c) after completion of the approach to implantation (CO or eRW), d) after sheath insertion, e) after electrode array insertion, f) after sheath withdrawal and g) after electrode lead positioning.

The compound-action potential (CAP) thresholds will be reported over time. The effect of each surgical stage on residual hearing will be inferred a shift in threshold. This approach may identify whether residual hearing is damaged prior

to insertion of the electrode.

• The position of electrode contacts relative to the modiolus, and the angular depth of insertion, and as assessed with pre- and post-operative CT-scan (TBD with HRCT-scans or UHRCT-scans and combined with micro-CT images, according to EIORL methodology). The trajectory of the electrode is expected to differ between the two surgical approaches. To assess whether this is the case, the position of each electrode contact (its angular dept of insertion and the distance of each electrode contact) will be measured, and the group measurements compared.

• Electrode measurements: TIM and NRT. If the electrode positions differ so may the thresholds of the eCAPs elicited by each electrode array. Therefore, the thresholds, plotted for each electrode along the array, will be compared between groups. Similarly, any electrode position between groups might be reflected in different profiles of the Trans Impedance Matrix.

# Study description

**Background summary**

In recent years, there has been a growing focus on the preservation of preoperative residual hearing in cochlear implant (CI) surgery. As the criteria for cochlear implantation have expanded, the significance of preserving residual hearing (RHP) has become increasingly evident. Beyond serving as an indicator of minimally traumatic implantation, RHP also enables natural sound perception in some CI patients and facilitates electrical-acoustic stimulation (EAS) in others. Studies have demonstrated that EAS can enhance sound localization and improve both music appreciation and speech recognition in

noisy environments. Consequently, the preservation of residual hearing has emerged as one of the main surgical goals in modern CI care. Nevertheless, there is still an ongoing discussion about the long-term benefit of preserving residual hearing in view of progressive hearing loss, either because of the natural progression of hearing loss or the presence of the electrode within the cochlea. A considerable amount of residual hearing should be present to be able to make use of the abovementioned benefits. Furthermore, recent findings seem to point out that preservation of acoustic input contributes to normal cortical activity following sound stimuli processed electro-acoustically rather than in the electric-only mode. In other words, maintaining peripheral acoustic hearing has central effects.

Using the slim modiolar electrode (SME), several potential sites of damage that may result in residual hearing loss can be envisioned. Firstly, concerning the approach to the cochlear lumen. This involves drilling at the promontory with potentially noise induced trauma to expose the round window (RW). Furthermore, the optimal entry site into the cochlea (extended round window (eRW) or cochleostomy (CO) which both imply drilling with bone dust or blood potentially entering the cochlea. If one would wish to choose for the CO approach and leave the RW anatomically intact, it is paramount to have an optimal position of the CO, to avoid damage. Secondly, damage may occur proximal in the basal turn of the cochlea on insertion of the sheath of the insertion tool hitting and transecting the basilar membrane, the osseus spiral lamina or the modiolar wall. Thirdly, further down the cochlea damage at the level of the basilar membrane may be the result of an ill-positioned, rotating electrode or a tip fold over.

Prospective cohort studies with this electrode involving postoperative CT-imaging have shown very different results in residual hearing preservation between the extended eRW and the CO approach. Recent observational data from the Radboudumc look favorable for the CO, as long as the electrode does not translocate to the scala vestibuli which in a prospective cohort study occurred relatively often and proximal in the basal turn. Anecdotally, several colleagues report the observation of immediate loss of residual hearing with the CI632 using the eRW approach. Sofar, the only explanation for short-term postoperative decline in threshold measured is the negative effect of stiffening of the RW membrane creating a cochlear conductive hearing loss.

Although we now have electrocochleography (ECochG) measurements available to suspect imminent damage occurring on insertion which could potentially prevent distal damage and translocation of the electrode, it has not yet been used to monitor what happens to the hearing during the insertion of the sheath. ECochG refers to the recording of electrical potentials generated by hair cells and auditory nerve in response to acoustic stimuli. ECochG can provide feedback about the cochlear structures during electrode insertion, based on which the surgeon can adapt the insertion to potentially reduce trauma. In addition, ECochG can shed light on which aspects of cochlear implant surgery are

detrimental for hearing preservation.

## Study objective

The aim of this study is to investigate whether the type of surgical approach to the cochlea; CO or eRW using the Nucleus 632 with the Slim Modiolar electrode affects the final residual hearing and secondarily, intracochlear trauma and electrode position.

Primary: To determine whether the surgical approach during implantation of the CI632 electrode affects residual hearing at 3 months post-implantation.

Secondary:
• To determine whether the surgical approach affects residual hearing when assessed at 1 week and 12 months post-implantation.
• To determine the stage of surgery at which the cochlear function is compromised, as measured by electrocochleography.
• To determine whether the surgical approach affects the intracochlear positioning of the electrode, as determined by pre- and postoperative CT-imaging.

Exploratory: To determine whether the surgical approach affects impedances and (e)CAPS at 6 weeks, 3 months, and 12 months post-implantation.

## Study design

This is a prospective, randomized control trial, in adult patients recommended cochlear implantation with Cochlear*s CI632 electrode. Participants will be randomized to one of two surgical approaches: extended round window or cochleostomy, with a 1:1 allocation in a parallel design.

## Intervention

Participants will be randomized to one of two surgical approaches: extended round window or cochleostomy.

## Study burden and risks

There are only minor additional risks to participation in this randomized clinical trial.
The implantation of the CI is a standard hospital procedure and the CI will be used within its licensed indication. Risks associated with the implant are detailed in product information available on the manufacturer*s website (see www.cochlear.com for company website).

In this study participants will be randomly assigned to undergo one of two

surgical approaches for cochlear implantation: the extended round window or cochleostomy. We will use an equal 1:1 allocation rate. Both surgical approaches represent standard care, ensuring that no additional risks will be introduced to the participants. The trial will be performed in a multicenter setting which may pose additional risk. However, as the sponsor we will ensure to have sufficient oversight of execution at the three participating centers which are internationally renowned implantation centers.

Moreover, one of the secondary objectives of this trial is to determine the stage of surgery at which the cochlear function is compromised, by means of electrocochleography. This ECochG measurement is CE marked. The surgeon will conduct the surgical procedure as per standard clinical practice, however, the ECochG measurement will take place intraoperatively. Intra-operative testing may prolong the surgical time. It is anticipated that the additional time required to conduct the intra-operative measurements will be no more than 30 minutes. This extension in the surgery duration may entail additional risks, such as those related to prolonged anesthesia and an increased risk of infection. These potential side effects are of moderate nature. The surgeon will use his/her discretion as to the acceptable extension to the operating time for each individual, and will terminate use of the ECochG tool as needed. All supplied equipment belonging to the ECochG measurement is non-sterile. There is potential for non-sterile equipment to enter the sterile surgical field. In order to mitigate this potential risk, all investigational sites must ensure the following non-sterile equipment is placed in a sterile bag(s): Freedom processor, RF coil and programming cable. The following non-sterile equipment must be isolated from the sterile field using the best surgical practices of the hospital performing the surgery: insert earphone foam tip and tubing.

Finally, the participant will encounter a small amount of burden due to the additional time required for one extra follow-up visit and the supplementary measurements conducted during this visit.

We are confident that this study represents negligible risks to subjects who consent to participate in this study.

As has been rationalized in the above section, study related risks are appropriately mitigated and reduced to acceptably low levels. Most of the clinical trial procedures align with standard care practices. The use of intraoperative ECochG measurements are CE-marked, and the additional surgical time required presents a negligible risk. Consequently, it is concluded that participation in this study and involvement in the intended study procedures pose no additional risks to the study subjects, ensuring their safety throughout the research.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)

## Inclusion criteria

• Participants >18 years old with severe sensorineural hearing loss
• CI candidate based on local criteria
• Cochlear implantation with a Cochlear Ltd. Slim Modiolar Electrode (CI632)
• Preoperative 500 Hz pure-tone threshold <80 dB hearing level under headphones in the ear to be implanted.

## Exclusion criteria

• Previous or existing cochlear-implant recipients.
• Patients with prelingual hearing loss.
• Patients with mixed hearing loss (air bone gap)
• Ossification or other cochlear anomaly that might prevent complete electrode

array insertion.
• Abnormal cochlear nerve anatomy on preoperative CT or MRI (excluding a Mondini malformation or large vestibular aqueduct syndrome)
• Deafness due to lesions of the acoustic nerve or central auditory pathway.
• Diagnosis of auditory neuropathy.
• Active middle ear infection.
• Medical or psychosocial conditions that would contraindicate participation in study evaluations.
• Unrealistic expectations from the participant regarding the possible benefits, risks, and limitations inherent to the CI procedure and the investigation.

# Study design

## Design

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| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Treatment |

## Recruitment

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| Recruitment status: | Pending |
| Start date (anticipated): | 01-10-2024 |
| Enrollment: | 20 |
| Type: | Anticipated |

## Medical products/devices used

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| Registration: | No |

# Ethics review

Approved WMO

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| Date: | 25-09-2024 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |

# 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 |
|---|---|
| ClinicalTrials.gov | NCT06453343 |
| CCMO | NL85808.091.23 |