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Characterisation of intra- and post-operative Neural Response Telemetry (NRT) recording parameters in Nexa cochlear implants

Submission date
21/05/2026

Recruitment status
Recruiting

Registration date
16/06/2026

Overall study status
Ongoing

Last Edited
29/06/2026

Condition category
Ear, Nose and Throat

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

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Public

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Study information

Scientific Title
Prospective within-subject exploratory study of intra-operative and post-operative NRT recordings using varying parameters in Nucleus® Nexa™ cochlear implant recipients

Acronym
NERT

Study objectives
This characterisation study is designed to compare Electrically Evoked Compound Action Potential (ECAP) recordings within participants using different sets of Neural Response Telemetry (NRT) recording parameters implemented in the Cochlear™ Objective Measures (COM) software.

Ethics approval required
Ethics approval required

Ethics approval(s)
Submitted 24/04/2026, Hospital aan de Stroom (ZAS) – Committee on Medical Ethics (Commissie Medische Ethiek) (CME) (Oosterveldlaan 24, Wilrijk (Antwerp), 2610, Belgium; +32 3 443 38 62; gza.ec@zas.be), ref: RL2026-608

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking

Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Basic science

Study type(s)

Health condition(s) or problem(s) studied
Evaluate ECAP recordings obtained using different NRT recording parameter configurations for participants already implanted with a Nexa cochlear implant or candidates for this implant.

Interventions
Adult Nexa™ implant users will undergo one research session accompanying a standard clinic visit or surgery. During this session, ECAP recordings will be performed with different NRT recording parameter settings in the COM software. In this study, COM is used during surgery and in clinic visits to support objective assessment of impedances, Trans Impedance Matrix (TIM), and NRT responses in Cochlear implant users and to provide a reference standard for evaluating the quality of ECAP recordings obtained during the investigation. The study includes randomisation of different parameter settings to be used. Participants will be assigned to their randomisation order based on the sequence of inclusion. Randomisation will follow a predefined randomisation schedule generated prior to study start. The schedule will be produced using a validated computer-based method to ensure allocation concealment and to minimise selection bias.

Intervention Type
Other

Primary outcome(s)
1. Within-subject repeated measurements of clinical impedances, measured using impedance values before vs. after conditioning, and postoperatively using the COM software at Visit 1 (intraoperative and postoperative)

2. Within-subject repeated measurements of NRT, measured using NRT thresholds before vs. after conditioning, and postoperatively across NRT configurations, using the COM software at Visit 1 (intraoperative and postoperative)

Key secondary outcome(s)

Completion date
31/12/2026

Eligibility

Key inclusion criteria

1. Implanted with a Nucleus CI1032/CI1022/CI1024/CI1012 or scheduled for Nucleus CI1032 /CI1022/CI1024/CI1012 implantation
2. 18 years or older (no upper age limit)
3. Sufficient speaker of Dutch to communicate with the investigator and correctly understand the informed consent form, as judged by the investigator
4. Willing to participate and comply with all requirements of the study protocol
5. Willing and able to provide written informed consent

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
100 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Diagnosis of auditory neuropathy
2. Additional health factors, known to the investigator, that would prevent or limit participation in the study
3. Unable or unwilling to comply with the requirements of the clinical investigation as determined by the Investigator
4. Investigator site personnel directly affiliated with this study and/or their immediate families; immediate family is defined as a spouse, parent, child, or sibling
5. Cochlear employees or employees of Contract Research Organisations or contractors engaged by Cochlear for this investigation
6. Pregnant or breastfeeding women, as reported by the participant
7. Current participation, or participation in another interventional clinical study/trial in the past 30 days, involving an investigational drug or device (unless Cochlear sponsored and determined by Investigator or Sponsor to not impact this investigation)

Date of first enrolment
07/06/2026

Date of final enrolment
31/12/2026

Locations

Countries of recruitment

Belgium

Study participating centre
European Institute for Otorhinolaryngology (EIORL) – Sint Augustinus Antwerp (ENT Department)
Oosterveldlaan 24
Wilrijk
Antwerp
Belgium
2610

Study participating centre
Cochlear Technology Centre Belgium
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Sponsor information

Organisation
Cochlear

Funder(s)

Funder type

Funder Name
Cochlear

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available