A prospective, multi-centre, repeated measures, traditional feasibility study investigating neural health correlates with outcomes and evaluating focused multipolar implementation in the Phoenix Research System for newly implanted adult cochlear implant recipients.

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Ethical review	Approved WMO
Status	Recruitment started
Health condition type	Head and neck therapeutic procedures
Study type	Interventional research previously applied in human subjects

Summary

ID

NL-OMON53745

Source
ToetsingOnline

Brief title
NEUROFI

Condition

- Head and neck therapeutic procedures

Synonym
hearing loss after development of speech post-linguistic bilateral sensorineural hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Cochlear AG
Source(s) of monetary or material Support: Cochlear AG

Intervention

- Medical device

Keyword: Cochlear implant, Feasbility Study, Prospective

Explanation

N.a.

Outcome measures

Primary outcome

1. To evaluate whether neural health metrics predict performance outcomes with
the MP ACE strategy post implantation
2. To compare sentence in noise performance for three NSC implementations; MP
SPACE, FMS SPACE and FMS Modified.

Secondary outcome

1. To compare words in quiet performance for three NSC implementations; MP
SPACE, FMS SPACE and FMS Modified.
2. To evaluate the benefit provided by NSC strategies for music appreciation
relative to the MP ACE strategy.
3. To compare subjective speech intelligibility, spatial and quality ratings
for MP SPACE, FMS SPACE and FMS Modified programs.
4. To compare speech perception performance outcomes for NSC strategies
relative to MP ACE.
5. To compare 6-month post implantation monosyllabic words in quiet scores with
MP ACE stimulation relative to State of the Art performance.
6. To compare 6-month post implantation subjective ratings of quality and
intelligibility with MP ACE stimulation relative to State of the Art
performance.
7. To evaluate safety data for the Phoenix Research System.

The study also has following exploratory objectives
• To characterize Electrode voltage Tomography (EVT) changes over time.
• To evaluate the relationship between changes in patient perception and

changes in objective speech perception metrics to inform minimum clinically
important differences for future studies.</p>

Study description

Background summary

The Phoenix System implant is a next generation cochlear implant with advanced stimulation capabilities compared to the standard cochlear implants. Phoenix Research System, comprising the Phoenix cochlear implant paired with the Nucleus 7 Smart sound processor, offers potential for improved hearing performance using Focused Multipolar Stimulation (FMS) through novel hearing paradigms. FMS narrows the spread of cochlear excitation from the active electrode, which is expected to improve the spatial selectivity and spectral resolution. FMS aims to enhance speech, environmental sound and music perception and provide real-world clinical benefits over current stimulation methods. There is potential to obtain further performance benefits over current stimulation methods by combining FMS stimulation with SPACE (Spread Precompensation Advanced Combination Encoder), a state-of the-art sound coding strategy. The SPACE investigational strategy, like FMS, aims to reduce cochlear spread of excitation, resulting in an increase spectral resolution.

Study objective

This traditional feasibility study intends to inform a future pivotal trial in the following two ways. Firstly, it aims to evaluate the potential of neural health metrics triggered by FMS, to predict the implant recipient*s auditory performance - the ability to use basic auditory cues. Secondly, it aims to inform future FMS program settings. The Novel Sound Coding (NSC) programs will be compared to the baseline program across a range of metrics, including word recognition in quiet, sentence recognition in noise, music appreciation and subjective ratings of speech intelligibility and sound quality. The NSC implementation that provides the best sentence in noise performance will inform the strategy that may be evaluated in a future pivotal trial.
The study aims to inform the development of a new sound coding strategy using the NSC. This study will investigate the potential benefits of the NSCs for sentence in noise recognition in addition to other performance metrics, including speech perception in quiet, music appreciation and subjective speech intelligibility and quality ratings.

Study design

The study is a prospective, multi-country, multi-center, traditional feasibility, single-blind, repeated measures investigation.

After surgical implantation and activation of the device, subjects will attend scheduled study visits over a 9.5 month study period. At study visits, subjects will undergo hearing assessments and safety assessments. This duration will be extended with annual safety monitoring visits if the CI1032 implant is not approved by end of Visit 8. The duration of the study itself is approximately two years, but will take longer if the CI1032 implant is not approved by Visit 8 of the last study participant.

Intervention

The CI1032 implant is the implanted component of a cochlear implant system and is used in conjunction with an externally worn sound processor in order to provide an auditory perception to patients. The implant system functions by providing electrical stimulation to surviving neural elements in the cochlea, bypassing the transduction mechanism normally provided by cochlear hair cells, which have typically been impaired or are absent in such individuals.

The electrode array is inserted into the cochlea, either through a small opening (cochleostomy) drilled by the surgeon or through an enlargement of the round window. Electrodes in the lower (basal) region of the cochlea, closest to the cochleostomy, stimulate auditory neural processes that perceive the high frequency sounds while the more distal (apical) electrodes stimulate the apical auditory neurons that perceive the lower frequencies. Further details on the electrode insertion technique are provided in the CI1032 Physician*s Guide.

Study burden and risks

Potential benefits specifically associated with participation in the clinical investigation include:
• Potential for improved hearing in areas such as speech perception, music appreciation, and sound quality through access to and experience with a wider range of stimulation paradigms than commercially available.
• Access to future product enhancements given that the research implant has firmware that can be upgraded.
• Access to a smaller commercial sound processor when it becomes available after completion of the study.
• Helping to find better treatments, therapies and/or diagnostic tests in the area of hearing loss.

The potential clinical risks associated with the investigational device include risks associated with receiving any cochlear implant. Risks specifically associated with this investigation are as follows:
• The procedures conducted in this study include a post-operative CT scan, which is not part of routine clinical care at all study sites. However, the exposure is minimal, with an estimated radiation exposure to 0,18 milliSievert, because only the inner ear will be exposed. The radiation dose to which an

average Dutch person is exposed per year is approximately 2.4 milliSievert (mSv).
• Malfunction of worn or implanted electronic medical devices other than the cochlear implant. The recipient will be advised to tell the study doctors and research staff if they have an electronic medical device implanted such as a pacemaker or a drug pump.
• During device programming there is a low risk that subjects may experience an uncomfortably loud or painful sound due to a software or firmware bug or clinician error. This risk is higher than with the predicate device implant, given that several novel programs will be created for the subject. The risk is mitigated by careful clinician training and software warnings.
• The CI1032 implant has built-in diagnostic tests to stop stimulation if any errors occur in the device, resulting in a restart of the device. If this happens the subject may experience a brief silence of up to 5 seconds until the implant restarts. There is a low chance that the implant will not restart, and in this situation the subject will need to attend the cochlear implant clinic for reset.
• The study schedule requires several changes in listening programs over the course of participation. Subjects may experience difficulty adjusting between programs.

There are also limitations associated with using the Phoenix Research System as listed below:
• Use of investigational stimulation strategies is restricted to participation in the study. Subjects will be required to use standard strategies following study completion, which may lead to disappointment if subjects preferred the investigational strategy. While it is possible that such strategies may become available following commercial approval, this is not guaranteed.
• Some accessories are not compatible with the investigational device, including the Aqua+ system for waterproof hearing, certain retention accessories and safety cords, telecoil, zinc air batteries, compact rechargeable battery, Nucleus Smart App and streaming for Android, Roger FM receiver, and Hybrid (electro-acoustic) hearing. Diagnostic features such as microphone automatic diagnostic (MicAD) will not be available. Surgical diagnostics will be limited to Auto-NRT and impedances. All of the above will be available following commercial approval of the CI1032 implant.
• For a period of time between the end of the study and availability of the commercial system, subjects will be limited to programming at the clinical site.
• Subjects are likely to experience a decrease in battery life for 3 months during the study whilst using some of the NSC programs. Subjects will be provided with extra rechargeable battery modules and battery charging units as required.

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Trial sites

Trial sites in the Netherlands

Amsterdam UMC
Target size: 19

Erasmus MC, Universitair Medisch Centrum Rotterdam
Target size: 3

Listed location countries

Italy, Germany, Netherlands

Eligibility criteria

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

Inclusion criteria

1) Individuals aged 18 years and older who have clinically established post-linguistic bilateral sensorineural hearing loss, and who have compromised functional hearing with hearing aids or would receive no benefit with hearing

aids and who meet candidacy criteria for cochlear implantation.
2) Fluent speaker in the language used to assess clinical performance as judged by the investigator. 3) Willing and able to provide written informed consent.

Exclusion criteria

1) Previous or existing cochlear-implant recipient.
2) Evidence of severe or greater sensorineural hearing loss in the ear to be implanted prior to two years of age as reported by the subject.
3) Pure tone average (average of unaided thresholds at 0.5, 1, 2 and 4 kHz) less than or equal to 30 dB HL in the better ear.
4) Adults with functional acoustic hearing in the ear to be implanted who desire to use an acoustic component post-operatively.
5) Ossification or other cochlear anomaly that might prevent complete insertion of the electrode array.
6) Diagnosis of auditory neuropathy.
7) Deafness due to lesions of the acoustic nerve or central auditory pathway.
8) Medical or psychological conditions that would contraindicate undergoing surgery.
9) Women who are pregnant.
10) Unrealistic expectations on the part of the subject regarding the possible benefits, risks, and limitations that are inherent to the surgical procedure and prosthetic device.
11) Unable or unwilling to comply with the requirements of the clinical investigation as determined by the Investigator
12) Investigator site personnel directly affiliated with this study and/or their immediate families; immediate family is defined as a spouse, parent, child, or sibling.
13) Cochlear employees or employees of Contract Research Organisations or contractors engaged by Cochlear for the purposes of this investigation.
14) Currently participating, or participated within the last 30 days, in another interventional clinical investigation/trial involving an investigational drug or device.

Study design

Design

Study phase:	N/A
Study type:	Interventional research previously applied in human subjects
Intervention model:	Crossover

Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment started
Start date (anticipated):	25-07-2023
Enrollment:	22
Duration:	11 months (per patient)
Type:	Actual

WORLD

Recruitment status:	Recruitment started
Start date (anticipated):	07-07-2023
Enrollment:	42
Type:	Actual

Medical products/devices used

Product type:	Medical device
Generic name:	CI1032 cochlear implant and CP1000 N7 sound processor
Registration:	No

IPD sharing statement

Plan to share IPD: No

Plan description
N.a.

Ethics review

Approved WMO

Date:	15-11-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	21-03-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	29-06-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-11-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-02-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-08-2024
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-02-2025
Application type:	Amendment
Review commission:	METC Oost-Nederland

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
Eudamed	CIV-NL-22-05-039515
CCMO	NL80621.000.22
Research portal	NL-007388