Spatial benefits of Beamforming in CROS Device for Cochlear Implant Users

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Main objective of this study is to characterize the possible benefits of the new Phonak Marvel CI-CROS device on speech understanding in noise, including its implemented beamformers (UltraZoom and StereoZoom) using different noise setups.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hearing disorders
Study type	Observational non invasive

Summary

ID

NL-OMON56534

Source
ToetsingOnline

Brief title
BF in CROS for CI

Condition

- Hearing disorders

Synonym
deafness, hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Anne van Alphen en Christiaan Stronks worden gefinancieerd vanuit een NWO subsidie (INTENSE project NWO Crossover grant). Het INTENSE project is een grootschalig project in samenwerking met vele onderzoeksinstanties patientenorganisaties en bedrijven. Er wordt co-funding ingebracht door bedrijven maar het

LUMC krijgt geen directe financiering vanuit deze bedrijven.

Intervention

Keyword: beamforming, cochlear implant, CROS, speech-in-noise

Outcome measures

Primary outcome

Speech Reception Threshold (SRT) in decibel.

Secondary outcome

Subject characteristics that could possibly influence the performance, for example residual hearing, duration of deafness, type of implant, electrode position in cochlea, duration of implantation, clinical Consonant-Vowel-Consonant (CVC) scores, demographics, participant ratings of sound perception with the loudness balancing feature of CROS device, and percentage of words correct in a sentence or SRTs with the CROS feature.

Study description

Background summary

A cochlear implant (CI) is a device placed in the inner ear of deaf patients, which can stimulate the auditory nerve. CI is the treatment of choice for severe to profound sensorineural hearing loss. In the Netherlands and other countries, implantation only of one side is covert by the insurance (Vickers et al., 2016). One pressing problem for unilateral CI users is that hearing with one ear leads to attenuated sound perception when speech is presented to the non-implanted side due to the head shadow effect. Further, CI users in general experience a marked reduction in speech intelligibility in noisy surroundings. The aim of this proposal is to test the contralateral routing of signals (CROS) system which is designed to eliminate the head shadow effect. In addition, CROS features state-of-the-art beamformers of the Phonak Marvel Contralateral Routing Of Signals (CROS) system and these will be tested for efficiency as well. Beamforming efficiency depends highly on the spatial aspects of the experimental setup.

Different setups are used by different research groups, making it harder to compare results between groups and draw conclusions. A comparison between most encountered setups and their effect on BF effectiveness has never been performed. To accomplish this, we want to conduct a study in normal-hearing (NH) and CI users to test different noise setups, to see the spatial effects of setups on the speech understanding. In addition, we also want to test the CI users in these setups to see the spatial benefits and effects of the new Phonak Marvel CROS device and the added UltraZoom and StereoZoom beamformers.

Study objective

Main objective of this study is to characterize the possible benefits of the new Phonak Marvel CI-CROS device on speech understanding in noise, including its implemented beamformers (UltraZoom and StereoZoom) using different noise setups.

Study design

This study is a single-centered cross-over trial. The total duration of the study is estimated to be 3 years. Normal-hearing and CI users are included as subjects in this study.

Intervention

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Study burden and risks

Normal-hearing subjects will participate in 2 sessions, the CI users participating in the CROS efficiency substudy in 2 sessions, and CI users participating in the beamforming in different spatial noise setups substudy in 3 sessions on non-consecutive days (number of sessions depending on how quick measurements go). Every session will take approximately 2-3 hours. Breaks can be included at every moment. The risk is considered negligible in this study, and the burden minimal. Attrition is accounted for in the subject calculation, making the groups large enough for a high power for the study. Because of this, this study is ethically justified. There will be no direct benefits for NH listeners or CI users.

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

Patients (cochlear implant users):
o Implanted with cochlear implant of Advanced Bionics on one side
o Minimum age of 18 years old
o Minimum of 6 months experience with their CI
o Speech understanding score (CVC phenome test) in quiet of at least 50%

Healthy subjects (normal-hearing):
o Minimum of 18 years old
o Normal-hearing, meaning an average pure-tone threshold of not more than 60 dB across a frequency of 500 - 4000 Hz

Exclusion criteria

- Disorders other than hearing impairment that could have an effect on study results
- Not able to complete 2 hours of consecutive testing
- Not fluent in Dutch

- Prelingual deafness

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-10-2024
Enrollment:	54
Type:	Actual

Medical products/devices used

Generic name:	Phonak Marvel CROS
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-02-2024
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	26-02-2024
Application type:	First submission

Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl
Approved WMO Date:	16-12-2024
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL85007.058.23