Binaural spatial enhancement study for cochlear implant users.

Published: 26-01-2023
Last updated: 18-01-2025

Determine speech understanding in noise with the AB*s bimodal BF directional hearing technology.

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

Summary

ID

NL-OMON51444

Source
ToetsingOnline

Brief title
BSE study

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: Nienke Langerak 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: Beamformer, Binaural, Cochlear implant

Outcome measures

Primary outcome

Speech recognition thresholds (SRT's) measured with the speech in noise tests.

Secondary outcome

Pure tone average of the audiograms, as well as the demographics of the

participants (duration of deafness, kind of implant, etc.)

Study description

Background summary

A cochlear implant (CI) is a prosthetic device for the inner ear, able to directly stimulate the auditory nerve. With a CI it is possible to bypass damaged inner hair cells and provide audible sensations to profoundly deaf implant recipients. The standard of care in the Netherlands, as well as the UK and other countries is unilateral implantation. Because detecting the direction where a sound comes from in the horizontal plane requires two functional ears, directional hearing is greatly impaired in CI users. If speech comes from the side, CI users understand speech less well. Speech understanding in noise is especially challenging for CI users, let alone when the speech comes from the contralateral side. If there is residual hearing in the contralateral ear, CI users can wear a hearing aid (HA) in that ear, which aids in speech understanding in noise. However, the performance of these so-called bimodal listeners is still very poor in terms of directional hearing, and speech understanding when speech comes from the HA side.
The company Advanced Bionics (AB) has various clinically used (and CE marked) speech enhancement strategies available to improve auditory scene analysis. Beamformers are one of them. They have been used for decades in the hearing aid industry and have more recently found their way in cochlear implants (Buechner, Dyballa et al. 2014, Vroegop, Homans et al. 2018). Beamformers are typically used to create a *beam* in front of the listener where sound passes unattenuated, and sound (noise) outside the beam is attenuated. This improves the signal-to-noise ratio and hence improves speech recognition in noise. Beamformers operate digitally at the input (microphone or front-end) level of the CI device and change nothing to the inner workings of the cochlear implant

at the auditory nerve level (back-end).
Beamformers can also be pointed to the sides, clinically referred to as *ZoomControl*. Combining the microphone signals from the CI and HA is called *StereoZoomTM*. By pointing the beams sideways (*ZoomControl*), speech coming from the sides can be improved. By combining both signals (*ZoomControl* + *StereoZoom*) the beams can be focused for more effective signal improvement.

Study objective

Determine speech understanding in noise with the AB*s bimodal BF directional hearing technology.

Study design

This will be an observational cross-over trial. The total duration of the study is estimated to be 1 year. It is a cross-over trial as every subject will be their own control when the speech understanding is tested in CI users, namely BF technique one and BF technique two switched ON (test) versus OFF (control). Speech understanding will be tested in 18 study participants.

Study burden and risks

This study is performed on CI users. The study is considered to involve negligible risk and minimal burden. Benefits to the CI population at large may be better speech understanding in noise. Given the small risk and high yield of this research it is an ethically justified study.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Implanted with a CI from Advanced Bionics at least on one side;
-18 years of age or older;
-At least 6 months experience with their CI;
-Measurable residual hearing in the non-implanted ear using audiometry with a threshold of at least 110 dB HL at one or more of the following frequencies: 125, 250 or 500 Hz

Exclusion criteria

-Disorders other than a hearing impairment that could affect the study results, such as psychiatric disorders or physical disorders that would limit their ability to undergo testing (e.g., movement disorders or blindness).
- not native Dutch speakers

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	05-05-2023
Enrollment:	18
Type:	Actual

Medical products/devices used

Generic name:	Monoaural side beamformer (MSBF);binaural side beamformer (BSBF);synchronized AGC (sAGC)
Registration:	No

Ethics review

Approved WMO

Date:	26-01-2023
Application type:	First submission
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	NL82175.058.22