Bilateral cochlear implantation and Phase-Lock Speech Coding (PLS), a pilot study

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Hearing disorders
Study type	Interventional

Summary

ID

NL-OMON32786

Source
ToetsingOnline

Brief title
Bilateral cochlear implantation and PLS

Condition

- Hearing disorders

Synonym
deafness, hard of hearing

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Doorhout Mees familiestichting

Intervention

Keyword: bilateral, cochlear implants, speech coding

Outcome measures

Primary outcome

Binaural function will be tested two ways: 1. Sound source indentification. Subjects are placed in a ring of sound speakers, separated by 15 degrees. They have to identify the source speaker for a range of sounds. The subject performance is expressed as the root mean square of the error angle. 2. Speech in noise recognition. Here the target speech and interfering noise are spatially seperated. The subject performance is measured in %-correct speech understanding.

Secondary outcome

Not applicable.

Study description

Background summary

Cochlear implantation is the primary therapy for profound deafness. A cochlear implant provides hearing by direct electrical stimulation of the auditory nerve. The translation from the acoustic sound, recorded by the implant*s microphone, to the electrical stimulus for the nerve is called the speech coding strategy. Several studies indicate that bilateral cochlear implantation, i.e. an implant in each ear, may provide significant advantages over single-sided implantation. These advantages are (1) a better ability to localize a sound source and (2) better speech understanding in listening situations with multiple interfering sound sources. These advantages are limited, presumably due to inherent limitations of the current speech coding strategies.

Study objective

The ENT clinic in Groningen has developed a new speech coding strategy: phase-lock speech (PLS) coding. This strategy distinguishes from existing strategies by the explicit coding of acoustic fine-structure. In normal hearing subjects, the advantages of binaural hearing depend in part on neural coding of acoustic fine-structure. It is hypothesized that PLS coding improves binaural hearing advantages over existing speech coding strategies by specifically coding the acoustic fine-structure. It is the primary goal of this project to test this hypothesis.

Study design

This is an exploratory pilot study, in which the hypothesis is tested by extensive binaural hearing tests.

Intervention

Subjects receive a second cochlear implant.

Study burden and risks

Subjects will undergo a second cochlear implantant surgery, followed by adjustment of the implant and hearing training. These procedures will be identical to the first implantation and are part of the standard medical care. Thus, subjects are familiar with the procedures. Surgical risks are identical to those of the first implant: (1) peri- and post-surgical infection, (2) dizziness and vertigo, (3) tinnitus, (4) loss of residual acoustic hearing function, if existing. The loss of residual hearing is usually compensated for by the cochlear implant. One month after surgery, the second implant will be adjusted using standard audiological procedures and using a standard speech coding strategy. After 3 and 6 months, the effect of bilateral implantation with the standard strategy will be tested. Then, the PLS strategy will be installed on the implant hardware. It*s effect will be tested immediately. Next, after one, and three months, binaural hearing with the PLS strategy is evaluated. Finally, subjects are re-adjusted to the standard strategy, which will be evaluated again after 3 months. Each audiometric testing session will last approximately 4 hours (including breaks).

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

- 18 years and older
- experience with a cochleair implant in one ear for at least 6 months

Exclusion criteria

- Subjects are excluded if the ear contralateral to the already implanted ear contains the only functional vestibular organ.

Study design

Design

Study phase:	2
Study type:	Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-02-2009
Enrollment:	3
Type:	Actual

Medical products/devices used

Generic name:	cochlear implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL24081.042.08