A randomized, double-blind, cross-over trial of two speech coding strategies in cochlear implantation

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Hypothesis: PLS will improve speech understanding in noise in comparison to HiRes, an exisiting state-of-the-art speech coding strategy. The objective is to test this hypothesis. A secondary hypothesis is that PLS improves pitch perception. A...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Interventional

Summary

ID

NL-OMON36103

Source
ToetsingOnline

Brief title
Comparison of two speech coding strategies in cochlear implants

Condition

- Inner ear and VIIIth cranial nerve 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: STW

Intervention

Keyword: cochlear implants, speech coding strategy

Outcome measures

Primary outcome

Main study parameters: Improvement of PLS over HiRes for a speech in noise

test.

Secondary outcome

Secondary outcomes are: improvement on a speech in quite test, improvement on a

frequency discrimination test, improvement on the SSQ questionnaire.

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. Current implant technology provides an impressive improvement of auditory function. However, one of the main limitations is a severe diffulty understanding speech in noise. In addition, the current implants are not able to transmit intonation in speech or melody in music. The ENT clinic in Groningen has developed a new speech coding strategy: phase-lock speech (PLS) coding. This strategy distinguishes itself from existing strategies by the explicit coding of acoustic fine-structure. A previous pilot study (METc reference 2008/167) suggested that PLS may lead to better speech understanding in noisy listening situations than an existing state-of-the-art strategy. In addition, PLS may improve the perception of pitch and melody.

Study objective

Hypothesis: PLS will improve speech understanding in noise in comparison to HiRes, an exisiting state-of-the-art speech coding strategy. The objective is to test this hypothesis. A secondary hypothesis is that PLS improves pitch perception. A secondary outcome of the study is a proof of the secondary

hypothesis.

Study design

A randomized, double-blind, cross-over trial of two speech coding strategies

Intervention

Intervention: A cochlear implant functions in conjunction with a dedicated external hearing aid, that is usually referred to as the speech processor. Subjects wear a body-worn speech processor during two study terms, each 3 weeks long. The processor replaces their usual behind-the-ear processor. During one term, the PLS is used. During the other term, HiRes is used. Hearing function is tested before the term start, and at the end of each term by audiometric testing and a questionnaire. The terms are separated by a period of 1 to 2 months, during which the subjects use their usual behind the ear processor.

Study burden and risks

Burden: During each of the two study terms, the subjects use a body worn processor. This processor can be worn e.g. on the belt, and connects to the implant via a wire and a standard head piece. It is less convenient than their usual clinical behind-the-ear processor. Each term involves three visits to the ENT-department of the UMCG: Day 1: for initial fitting of HiRES or PLS and questionnaire, duration: 1.5 hour, Day 8: second fitting session for fine tuning of HiRes or PLS. Day 21: audiometric assessment, completing quessionaire, duration 2.5 hour.
Risk: There is no known risk associated with participation.
Benefit: There is no direct benefit for the participatiors. The study is intended to test a technique from which subjects may profit in the future.

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 cochlear implant for at least six months
- Advanced Bionics Inc. cochlear implant
- Able to participate in fitting and testing session

Exclusion criteria

No or very poor ability to understand speech with the cochlear implant and it*s current speech processing strategy, as evidenced by a phoneme score <40% in standard speech audiometry.

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-09-2011
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	speech processor of a cochlear implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	23-08-2011
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	NL35637.042.11