ELEPHANT

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20963

Source
Nationaal Trial Register

Brief title
ELEPHANT

Health condition

cochlear implant
deafness
clinical trial
tonotopy

cochleair implantaat
doofheid
klinische trial
tonotopie

Sponsors and support

Primary sponsor: Maastricht University Medical Center+
Source(s) of monetary or material Support: Advanced Bionics

Intervention

Outcome measures

Primary outcome

To evaluate the effect of natural place-pitched electric mapping, the following outcome measures will be compared between the new fitting strategy under investigation (Test) and the standard clinical fitting (Control):

- Objective primary outcome: degree of speech understanding (words in quiet, sentences in quiet, sentences in noise) with CI during the first 6 months of rehabilitation.

- Subjective primary outcome: patient preference in daily life for either the natural fitting or clinical fitting during the first 6 months of rehabilitation.

with CI

Secondary outcome

Secondary outcomes include objective and subjective measures to reflect biological response, performance, preference and sound quality:

- Telemetric data on the function of the implant and the response of the auditory nerve.

- Speech understanding with the contralateral HA (acoustic input) and bimodally (CI+HA)

- Extended dimensions of sound perception (spatial masking, listening effort, sound quality, spectral resolution, loudness scaling).

- Quality of life in relation to hearing ability.

Study description

Background summary

In search of the best possible outcome for the severe hearing impaired who have regained the ability to hear by means of a cochlear implant (CI), electrical stimulation and the information it carries should match as closely as possible to what the human brain naturally has evolved to cope with and learned to process instead of relying on plasticity to adapt to an induced mismatch. At the moment, however, CI’s are fitted with a ‘one size fits all’ principle. This is known to cause a mismatch between the frequencies presented by the CI electrode array and the frequencies represented at the corresponding natural acoustic location in an individual cochlea.

In this study it is hypothesized that an individual imaged based fitting that pursues natural hearing alignment and is implemented from the start of the rehabilitation process, will improve the individual outcomes of electric hearing. The natural fitting strategy is thought to

give rise to a steeper learning curve, result in a better performance in challenging listening situations, improve sound quality, complement better with residual acoustic hearing in the contralateral ear and win the preference of CI-recipients.

Study objective

In this study it is hypothesized that patients with a cochlear implant will benefit from an individual imaged based fitting that pursues natural hearing alignment and is implemented from the start of the rehabilitation process.

Study design

This study has multiple phases. The primary part is set up as a prospective single blinded, daily randomized cross-over clinical trial. In this phase electric hearing will be optimized. When patients retain the use of a contralateral hearing aid, acoustic hearing optimization will be performed in a second phase. During the third phase, patients receive their clinical fit, which will be based on the preferences they have obtained during the study period. More in detail, the study outline can be summarized as follows.

- Phase 1. During the intensive CI-rehabilitation phase, mapping of the electrical input will be based on an individualized natural frequency alignment as estimated with imaging methods. This natural fitting will be compared to the standard frequency alignment. A daily randomization scheme will be applied whereby the subject crosses over between CI fitting programs and thus effectively acting as his own control, followed by a period of free choice between both maps to incorporate patient preference. Outcome measures will be assessed at several single points, to address the difference between both CI maps, as well as over time, to address the learning curve with both CI maps.

- Phase 2. After a period of 6 months a stable outcome with CI is expected. When patients retain the use of a contralateral hearing aid up to this time point, the fitting of the acoustic hearing aid will be optimised and compared to the standard fitting. Outcome measures will be assessed acutely and at the end of a take-home period.

- Phase 3. At this time point, patients have indicated their final preference for either the conventional or bimodal HA fitting. In combination with the preferred CI settings, as indicated at the end of phase 1, a clinical fit will be performed for both CI and HA.

Intervention

Two interventions will be implemented during the study.

1. During the intensive CI-rehabilitation phase, mapping of the electrical input will be based

on an individualized natural frequency alignment as estimated with imaging methods. This natural fitting will be compared to the standard frequency alignment. A daily randomization scheme will be applied whereby the subject acts as his own control, followed by a period of free choice between both maps. Outcome measures will be assessed at several single points, to address the difference between both CI maps, as well as over time, to address the learning curve with both CI maps.

2. In a second stage, after a stable outcome with CI is reached and if a contralateral hearing aid is used, the fitting of the acoustic hearing aid will be optimised and compared to the standard fitting. Outcome measures will be assessed acutely and at the end of a take-home period.

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Eligibility criteria

Inclusion criteria

• Adult (18y or older) and meeting the conventional Dutch CI criteria;

• Proficient speaker of Dutch language;

• Post-lingual onset of profound deafness (> 4 years of age);

• Subject receives an Advanced Bionics implant with Midscala electrode and an Advanced Bionics sound processor;

• Prepared to use a study specific hearing aid (Phonak) for the duration of the study;

• Rehabilitation at MUMC+ for the first year after surgery regarding CI as well as HA;

• Active participation in trial related procedures such as daily randomization and regular testing.

Exclusion criteria

• Physical or non-physical contraindications for MRI or CT imaging;

• Additional disabilities that may prevent active participation and testing as per protocol. If there are indications that the mental abilities to comply with the study procedures are insufficient, additional screening will be performed with the Mini-Mental State Examination. Patients will be excluded from the study when the resulting score is lower than 24;

• Cochlear or neural abnormalities that could affect outcome measures and/or compromise the placement of the electrode as assessed by the CI surgeon;

• Active participation in another prospective clinical trial;

• Pregnancy at time of imaging;

• Requirement for electric-acoustic activation prior to the first year follow-up;

• Having received a cochlear implant earlier (e.g. explantation or bilateral implantation).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial

Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2018
Enrollment:	30
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 52955
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5049
NTR-old	NTR7447
CCMO	NL64874.068.18
OMON	NL-OMON52955

Study results