Societal merit of Intervention on hearing Loss Evaluation (SMILE)

Published: 06-11-2019
Last updated: 10-04-2024

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Ethical review	Not approved
Status	Will not start
Health condition type	Hearing disorders
Study type	Interventional

Summary

ID

NL-OMON48029

Source
ToetsingOnline

Brief title
SMILE

Condition

- Hearing disorders

Synonym
Patients with some residual hearing, Severe Hearing loss

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Heinsius-Houbolt Fonds

Intervention

Keyword: Cochlear implants, Prevention, Residual Hearing, Societal

Outcome measures

Primary outcome

Participation is the primary outcome of the study and is measured by using the Impact on Participation and Autonomy (IPA) questionnaire. The primary parameters are obtained by the domains family role; social life and relationships; and work and education.

Secondary outcome

Autonomy measured by IPA; domains: Autonomy outdoors, autonomy indoors.

Communication profile Measured by the Amsterdam Questionnaire for Hearing Impairment and labour. The used domains are: Maladaptive behaviour, verbal strategies, non-verbal strategies, self-acceptance, acceptance of loss, stress and withdrawal.

Work Measured by using the Amsterdam Questionnaire for Hearing Impairment and labour. The used domains are: Need for Recovery, participation, and relation to co-workers.

Productivity loss measured by the Productivity Costs Questionnaire.

Quality of life questionnaires (the generic HUI-3 and the disease specific NICQ) will be used in this study and are already part of standard clinical

practice.

Capabilities are measured by using the ICECAP-A questionnaire and by conducting semi-structured interviews.

Cognition is measured by using the RBANS-H cognition test.

Listening effort is measured by pupillometry.

Study description

Background summary

Cochlear implantation (CI) has been successful in terms of rehabilitation of severe to profound hearing loss. CI in adults with severe to profound hearing loss resulted in significant gains in quality of life and psychosocial wellbeing. In addition, cost-effectiveness of unilateral CI in adults with severe to profound hearing loss has been demonstrated in various publications. Most adults with moderate to severe hearing loss, show a decline in speech recognition with progression of their disability, even when fitted with hearing aids. Their disability might progress to a state in which societal participation becomes difficult: the disability might influence social participation, autonomy, work/occupational status and quality of life. In recent years, due to improved outcome following CI technology, audiologic and functional inclusion criteria for CI have broadened. As a result, more people have become eligible for CI. Moreover, the number of patients who might benefit from a CI is expected to increase further. Besides the expanded indication there is an increase in awareness about CI effectiveness among the eligible population. Also, due to the aging population more elderly will become eligible for CI. This has resulted in increased waiting lists of almost two years in some centers in the Netherlands. In this waiting period the patient*s condition might be worsening.
It is hypothesized that after 1 year of CI use by patients with severe hearing loss, there is an improvement on societal related outcomes compared to the control group with conventional hearing aids. In addition, there is little to no evidence about the potential societal benefits from early implantation. In this study patients will receive early implantation in the intervention group

and the control group before they progress to profound hearing loss or deafness.
A long-term observational study is of importance to determine cost-effectiveness, in which participants function as their own controls in a within subject analysis. It is important for its scientific content but also for its implications for healthcare policy. A similar study has not been conducted yet.

Study objective

The primary objective of this study is to determine the effect of intervention with a CI in post lingual adult patients with progressive severe hearing loss and thus residual hearing, compared to standard care with hearing aids, on societal related outcomes (participation; communication profile; autonomy; cognition; listening effort; work; productivity loss; quality of life and capability.)
The secondary objective is to determine the long term effects of CI in post lingual adults with severe hearing loss on the same societal related outcomes in an observational manner.

Study design

Randomized controlled trial followed by a prospective observational study.

Intervention

The primary intervention of this study is a CI at severe hearing loss compared to best fitted hearing aids. To achieve this comparison participants will be randomly divided into two groups. Participants in the intervention group will receive a CI with an accelerated trajectory. Participants in the control group will receive a CI according to the current standard trajectory.
By making this division we create a time period in which the intervention group has a CI and the control group still uses hearing aids. Till this point in time the comparison for answering our primary research question is possible.

Study burden and risks

In our view there is a relatively small additional burden by participating in this study in relation to the standard CI procedure. In addition, we do not foresee any health risks associated with study participation.
In this study we try to schedule study measurement appointments on moments when the patient already visits the hospital for regular care.

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

Inclusion criteria are closely related to the clinical eligibiltiy criteria maintained at the medical center.
In addition:
1.) Age between 18-65 years, the working population.
2.) Participants have severe post *lingual sensorineural hearing loss (as defined by WHO criteria of 61-81 dB loss).
3.) Eligible for CI based on clinical criteria and on the following audiometric data:
- best aided phoneme score * 70% at 65/70dB HL
- Communication need
4.) Sufficient understanding of the Dutch Language.

Exclusion criteria

The following exclusion criteria are maintained for the study.
1.) Patient has an underlying syndrome.
2.) Pre-lingual Hearing impaired individuals.
3.) Sudden hearing loss.
4.) Children 0 * 18 years old.
5.) Elderly 65+ years old.
6.) Profound hearing loss
7.) Any condition that may hamper a complete insertion of the electrode array or a normal rehabilitation with the cochlear implant (severe otosclerosis or neurologic deficits)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	70
Type:	Anticipated

Ethics review

Not approved

Date:	06-11-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL70869.091.19