Tinnitus implant: Tinnitus and cochlear implantation

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

Summary

ID

NL-OMON54676

Source
ToetsingOnline

Brief title
Tinnitus and cochlear implantation

Condition

- Hearing disorders
- Head and neck therapeutic procedures

Synonym
moderate to severe tinnitus

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Cochlear Ltd.

Intervention

Keyword: cochlear implantation, electrical stimulation, Tinnitus

Outcome measures

Primary outcome

The main outcome will be the difference of the tinnitus functional index (TFI) between the intervention (CI) at 6 months after cochlear implantation (CI) and the control group at 6 months after randomization.

Secondary outcome

Secondary outcome measures will be:

- Anxiety and Depression level: BDI, HADS

- Electrocochleography

- Hearing level: pure tone audiometry at 0.25, 0.5, 1, 1.5, 2, 4 kHz

- Hearing related QoL: SSQ

- General QoL: EQ5D

- Patient reported change: GBI and CGI

- Tinnitus severity: VAS

- Tinnitus pitch and loudness matching

- Speech recognition test in quiet and noise

The usage of CI and the hearing environment on daily average will be logged from the sound processor.

Study description

Background summary

Tinnitus is the perception of sound without an external stimulus, often experienced as a ringing or buzzing sound (Zeman, Koller, Schecklmann, Langguth, & Landgrebe, 2012)(Moller, Salvi, De Ridder, Kleinjung, & Vanneste, 2015). While the underlying aetiology of tinnitus is still debated, one hypothesis is that the tinnitus arises from changes in neural activity caused by reduced or lack of auditory input due to hearing loss which often accompanies the tinnitus (JJ & LE, 2017) (Moller et al., 2015). Tinnitus is a common symptom with an approximate prevalence of 10-30%, depending on the selected population (Møller AR, Langguth B, De Ridder D, 2010) (Davis A, 2000). Since no curative treatment for tinnitus is available until today, symptom reduction is the highest possible effect. This study will focus on the effect of a cochlear implant (CI) to treat tinnitus.

Study objective

The main objective of the study is to assess the effect of a cochlear implant on tinnitus burden in patients suffering from tinnitus accompanied by hearing loss.

Study design

50 patients with complaints of moderate to severe tinnitus (TFI>32 and tinnitus duration >1year) and moderate to severe hearing loss (PTA at 0.5,1,2,4 kHz: bilateral threshold >= 40 and <= 80 dB and hearing thresholds in the ear to be implanted (>= 4 kHz) >= 50 dB) will be included in this randomized controlled trial (RCT) after their Informed Consent (IC). 25 patients (CI group) shall receive a CI in the ear mostly affected by tinnitus.. The other 25 patients (control group) shall follow the same follow up period of 6 months with no intervention. The follow-up sessions will take place 3, and 6 months after implantation to assess the primary outcome of tinnitus burden and secondary outcomes of quality of life, treatment related outcomes and auditory function.

Intervention

Patients from the intervention group will be surgically implanted with a CI from Cochlear Ltd under general anesthesia on the most tinnitus affected side. A phase of rehabilitation and a phase of follow-up including auditory evaluations and questionnaires will be followed by all patients from the intervention group. Patients from the control group will have no intervention and will follow the same auditory evaluations and questionnaires as the intervention group.

Study burden and risks

The study is considered as a risk-benefit investigational treatment. The cochlear implantation is a standard treatment under general anesthesia in

current clinical care in case of more severe levels of bilateral hearing loss. In this study, individuals with moderate hearing loss are included, which induces a risk of deterioration of hearing threshold that needs to be considered because of the cochlear trauma during the cochlear implantation. On the other hand, the tinnitus may benefit from cochlear implantation and result in tinnitus suppression (Arts 2016) and may restore the hearing loss. The study includes a series of questionnaires to be filled in at home at 2 weeks, 3 and 6 months after implantation and auditory function tests at 3 and 6 months after implantation in the clinic (approximately two hours each).

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

• Patients aged 18 or older

• Seeking help for tinnitus
• Subjective tinnitus
• Tinnitus Functional Index (TFI) > 32
• Tinnitus duration > 1 year and subjective tinnitus stability > 6 months
• Hearing level:
o Audiometry (Pure Tone Average (PTA) at 0.5,1,2 kHz): bilateral threshold >= 40 and <= 80 dB
o Hearing thresholds in the ear to be implanted (>= 4 kHz) >= 50 dB
o Hearing threshold stability (PTA < 5 dB change for 1 year in each ear)
• Health status allows general anesthesia and surgery for the cochlear implantation
• Failure of regular tinnitus care (e.g. psychological or sound therapy)
• Dutch language proficiency
• Willingness and ability to participate in all scheduled procedures outlined in the protocol
• Able to understand and sign informed consent

Exclusion criteria

• Patient primary seeking help for non-tinnitus hearing problems
• Abnormal cochlear anatomy(i.e. ossification)
• Comorbidity with an expected survival of less than five years based on medical history as assessed by clinician and in electronical patient file
• Additional handicaps that would prevent participation in the evaluations
• Presence of any instable psychiatric condition within 6 months before start of the study
• Patient with active clinical depression within the 6 months before start of the study
• Unrealistic expectations on the part of the patient regarding the possible benefits, risks and limitations that are inherent to the procedure

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-03-2021
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Nucleus Cochlear Implant
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	07-04-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	18-11-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	16-03-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	07-06-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	18-07-2023
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 23880
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL70319.041.19
OMON	NL-OMON23880