Tinnitus implant: tinnitus and cochlear implantation

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23880

Source
Nationaal Trial Register

Brief title
Tinnitus implant

Health condition

tinnitus, bilateral hearing loss, bilateraal gehoorverlies

Sponsors and support

Primary sponsor: Department of Otorhinolaryngology and Head & Neck Surgery University Medical Center Utrecht, Utrecht, The Netherlands
Source(s) of monetary or material Support: Cochlear

Intervention

Outcome measures

Primary outcome

Difference of the Tinnitus Functional Index (TFI) between the intervention group (CI group) at 6 months after cochlear implantation (CI) and the control group at 6 months after randomization

Secondary outcome

Secondary objectives are to assess change in:
- Beck's Depression Index (BDI)
- Handicap Anxiety and Depression Scale (HADS)
- Electrocochleography (ECochG)
- Pure tone audiometry at 0.25, 0.5, 1, 1.5, 2; 4 kHz
- Speech, Spatial and Qualities of hearing scale (SSQ)
- EuroQoL5D
- Glasgow Benefit Inventory (GBI)
- Clinical Global Impression (CGI)
- Tinnitus severity Visual Analogue Scale (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

Rationale: Tinnitus is the perception of sound without an external stimulus, often experienced as a ringing or buzzing sound. 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. Tinnitus is a common symptom with an approximate prevalence of 10-30%, depending on the selected population. 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.

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 (Tinnitus Functional Index (TFI)>32 and tinnitus duration >1year) and moderate to severe hearing loss (pure tone average at 0.5,1,2,4 kHz: bilateral threshold between 50 and <75dB) 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.

Study population: The study population consists of patients seeking help for tinnitus,

presenting at the outpatient clinic of ENT of the UMC Utrecht, The Netherlands. 50 patients aged 18 or older with moderate to severe tinnitus and moderate to severe hearing loss will be included after fulfilling eligibility and informed consent.

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 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 objective

Significant difference between the cochlear implant recipients and the control group for tinnitus burden at 6 months post-implantation

Study design

Baseline and 3 and 6 months post-implantation (CI group)
Baseline and 3 and 6 months after randomization (control group)

Intervention

Randomised:
Cochlear implantation versus no intervention

Contacts

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Eligibility criteria

Inclusion criteria

- Patients aged 18 or older
- Seeking help for tinnitus
- Subjective tinnitus
- Tinnitus Functional Index (TFI) > 32
- Tinnitus duration > 1 and tinnitus stability > 6 months
- Hearing level (measured with a maximum of 3 months before eligibility assessment):
> Audiometry (Pure Tone Average (PTA) at 0.5,1,2,4 kHz): bilateral threshold between 50 and < 75 dB
> Hearing threshold stability (PTA < 5 dB change for 1 year in each ear)
- Becks Depression Inventory (BDI) <19
- 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 1 year 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)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2021
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
All of the individual participant data collected during the trial will be made available, after deidentification. Study protocol, statistical analysis plan, informed consent form, clinical study report and analytic code will also be made available. Data will be shared immediately following publication, without an end date. It will be shared with researchers who provide a methodologically sound proposal, to achieve aims in the approved proposal.

Ethics review

Positive opinion

Date:	05-06-2020
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 54676
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL8693
CCMO	NL70319.041.19
OMON	NL-OMON54676

Study results