# 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 Cl 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
  - 4 Tinnitus implant: Tinnitus and cochlear implantation 23-05-2025

- 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

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

# Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	09-03-2021
Enrollment:	50
Туре:	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	18 11 2020
Date:	10-11-2020
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: Nationaal Trial Register Title:

## In other registers

Register	ID
ССМО	NL70319.041.19
OMON	NL-OMON23880