Implantation of an auditory brainstem implant for the treatment of incapacitating unilateral tinnitus

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To evaluate the efficacy of an ABI for the suppression of unilateral, intractable tinnitus and to establish the safety of the ABI for this new indication.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Interventional

Summary

ID

NL-OMON47290

Source
ToetsingOnline

Brief title
ABI for tinnitus

Condition

- Inner ear and VIIIth cranial nerve disorders
- Nervous system, skull and spine therapeutic procedures

Synonym
tinnitus

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: MED-EL

Intervention

Keyword: ABI, neurostimulation, tinnitus

Outcome measures

Primary outcome

The primary outcome is change in the Tinnitus Functioning Index (TFI). The endpoint is set at 1 year after implantation. Follow up will take place until 5 years after implantation.

Secondary outcome

• Safety: changes in hearing as measured by pure tone audiometry (PTA) and speech discrimination tests from baseline to follow up; changes in vestibular function as measured by vestibular tests between baseline and 3 months after initial stimulation with the ABI.

• Change in TFI from 12 months to 5 years of follow up (long term effect).

• Change in VAS (visual analogue scale)-scores (tinnitus loudness, tinnitus annoyance) from baseline to follow up.

• Change in HADS-scores (Hospital Anxiety and Depression Scale) from baseline to follow up.

• Change is THI-scores (Tinnitus Handicap Index) from baseline to follow up.

• Tinnitus matching from baseline to follow up.

Study description

Background summary

Tinnitus is the perception of sound or noise in the absence of an external physical source. It is a highly prevalent condition and for a high percentage

of patients, there is no satisfying treatment modality. For some people, tinnitus has a very severe impact on quality of life, leading to incapacity for work and sometimes even suicidality. The auditory brainstem implant (ABI) is an implant indicated for the restoration of hearing in patients with an hypo-, or aplasia of the cochlear nerve or with dysfunction of the nerve caused by tumor growth in neurofibromatosis type II. It has been shown that the standard intended effect of an ABI has reduction of tinnitus as a welcome side effect in about 66% of the cases. This is in analogy with the promising effect of a cochlear implant (CI) as a treatment for patients with unilateral tinnitus. In this study, the effect of an ABI on severely invalidating, unilateral, intractable tinnitus will be investigated. The ABI may have an advantage over the CI as tinnitus treatment, because CI-implantation leads to destruction of inner ear structures, leading to profound deafness, while an ABI is presumed to not damage anatomical structures. This is the first study to implant an ABI for the primary aim of tinnitus reduction.

Study objective

To evaluate the efficacy of an ABI for the suppression of unilateral, intractable tinnitus and to establish the safety of the ABI for this new indication.

Study design

This is a single center, non-randomized, prospective cohort, intervention pilot study. There is no control group. In this study, 10 patients will be implanted with an ABI.

Intervention

All study participants receive an ABI, which will be neurosurgically implanted. The ABI will be switched on 6 weeks after implantation. The surgery and post-surgery follow-up and switch-on procedures are consistent with the intended use of the ABI.

Study burden and risks

The implantation, activation and fitting of the ABI will be performed exactly as described in the existing protocols for intended use, however in this study, the ABI is placed for another indication. Implantation of the ABI requires hospital admission for estimated 4 days. After dismissal, patients visit the outpatient clinic at least 8 times in the first year, depending on the amount of fitting session necessary. Implantation of the ABI is an invasive procedure, which potentially can cause severe complications (meningitis 3,8%, transient hydrocephalus 1,3%, cerebellar contusion 1,2%). Other complication that may occur are infection, bleeding, hearing loss and other cranial nerve

dysfunctions. By an extensive training program for the neurosurgeon and presence of the experienced surgeon during the first surgical procedures, we feel that neurosurgical risks and risk of device failure due to inadequate implantation can be limited. In this pilot study, the effects on hearing and tinnitus are still uncertain, however based on the results published in literature we are confident that the effects on both will be positive. Nonauditory side-effects and disappointing results on hearing and/or tinnitus can be well managed by altering stimulation strategy or if necessary, by turning off the device. Tinnitus can be severely invalidating with a large impact on quality of life and the ABI is promising in reducing tinnitus in these patients. This study imposes a significant risk on the study participants. However, we feel that the risks outweighs the potential to ameliorate severely debilitating tinnitus.

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

- Unilateral tinnitus
- Severely invalidating tinnitus
- Men or women, age >18yr
- Tinnitus that is present >1 years and was stable during the last year
- Tinnitus that is nonresponsive to indicated conventional existing treatments (hearing aids and cognitive behavioral therapy. If a psychologist has indicated that CBT may ameliorate tinnitus complaints, the patient should have tried CBT for long enough time to reasonably argue that these treatments were not successful. This is the same for hearing aids.
- Ipsilateral ear: pure tone audiometry (PTA) thresholds >=40dB and <=90 dB (mean over 1-2-4 kHz).
- Functional hearing in the contralateral ear with PTA thresholds <=35dB with a minimal Δ25dB compared to the other (ipsilateral) ear.
- Informed consent after extensive oral and written information about the surgery, complications and the uncertain effect of the ABI on tinnitus
- Acceptable overall physical condition as declared by an anesthesiologist
- No detectable cause for tinnitus that requires causal therapy (e.g. glomus tumor, otosclerosis, arterio-venous malformation) as investigated by medical and otological examination

Exclusion criteria

- Psychiatric pathology and/or an unstable psychological situation as declared by a psychiatrist
- Unrealistic expectations as declared by the investigator and/or psychiatrist
- Life expectancy <5 yr
- History of blood coagulation pathology
- ASA >II
- Pregnancy
- Anatomic abnormalities that would prevent appropriate placement of the stimulator housing in the bone of the skull
- Anatomical abnormalities or surgical complications which might prevent placement of the ABI Active Electrode Array
- If the individual is known to be intolerant of the materials used in the implant (medical grade silicone, platinum, iridium and parylene c)

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	28-07-2016
Enrollment:	10
Type:	Actual

Medical products/devices used

Generic name:	auditory brainstem implant
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	13-06-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-06-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	16-05-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	21-01-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL55276.042.15