Cochlear*s Direct Acoustic Cochlear Stimulator Investigational Device (C-DACS ID) clinical trial CAG5229

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

Summary

ID

NL-OMON34163

Source
ToetsingOnline

Brief title
C-DACS clinical trial CAG5229

Condition

- Hearing disorders

Synonym
fixation of the stapes, Otosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Cochlear AG
Source(s) of monetary or material Support: Cochlear AG

Intervention

Keyword: C-DACS ID, Cochlear, Middle Ear Implant, Otosclerosis

Outcome measures

Primary outcome

Audiological: aided free field hearing thresholds and scores of speech

discrimination.

Chirurgisch: complication registration and bone conduction thresholds.

The subjective experiences of the participants will be tested by the APHAB

questionnaire.

Secondary outcome

nvt

Study description

Background summary

One of the common causes leading to conductive hearing loss is otosclerosis. In general, otosclerosis leads to a fixation of the stapes footplate to the oval window of the cochlea. This generally impairs movement of the stapes and therefore transmission of sound into
the inner ear. Otosclerosis is predominantly a Caucasian disease. Its prevalence lies between 0.1% and 1% with a mean prevalence of 0.3%. The incidence of otosclerosis is approximately two times higher in woman than in men. Usually noticeable hearing loss begins between the
age of 15 and 45, but can start sooner . In most cases the disease is bilateral. 75% of patients have additional tinnitus.
Despite intensive research. the aetiology of otosclerosis is not fully understood. Treatment of otosclerosis relies on two primary options: hearing aids (more recently including Baha) or stapes surgery. Hearing aids are usually very effective early in the course of the disease, but
eventually a stapedectomy may be required for definitive treatment. Stapedectomy is indicated when the stapes is firmly fixed, as demonstrated by an air-bone gap of at least 30 dB for the speech frequencies and a negative Rinne test. If the conductive component of a mixed hearing loss is still quite

small (< 30 dB) hearing aids can be used to compensate for both components of the hearing loss. But the need for high amplification can drive even the most powerful hearing aids to their limits and introduce problems with distortion.
If the conductive component of a mixed hearing loss is still quite small (< 30 dB) hearing aids can be used to compensate for both components of the hearing loss. But the need for high amplification can drive even the most powerful hearing aids to their limits and introduce problems with distortion
Implantable hearing aids are commercially available since a few years. They were originally developed for the compensation of sensorineural hearing losses and to remove problems with stigma, occlusion and discomfort. Lately, implantable hearing aids are also used to compensate for conductive or mixed hearing losses.
A middle ear implant consists of two parts, a subcutaneous receiver and a transducer which is attached to the stapes or incus. An external soundprocessor is carried. In this way sounds are transferred to the middle ear without the need to occlude the external ear canal.
With the newly developed system of direct acoustic cochlear stimulation (DACS) a middle ear implant is placed in combination with the prosthesis of stapedotomy the surgery. The prosthesis is not attached to the body of the incus but on a artificial incus. In this way a solution can be put forward for patients with mixed hearing loss involving the conductive component (using the prosthesis) and the perceptive component (using the C-DACS system).

Study objective

The basic safety of the surgical procedure and the DACS actuator as well as the basic efficacy of the DACS were already shown in the DACS Chronic Clinical Trial (see protocol). The safety of the C-DACS ID receiver/stimulator, which replaces the percutaneous plug, is shown since many years in CE marked cochlear implants. The C-DACS Clinical Trial has three main objectives. The first trial objective is to confirm the clinical
efficacy of the C-DACS ID in subjects with severe to profound mixed hearing loss. This will be done by measuring and analyzing the aided free field hearing thresholds and aided speech discrimination scores post-operatively.
The second trial objective it to investigate a new fitting algorithm for the C-DACS ID. The new fitting algorithm is based on the expected most comfortable level of the subject, calculated with the in-situ thresholds and in-situ UCL measured during the fitting procedure. The new fitting algorithm is expected to deliver a good first impression of the sound quality at the activation of the C-DACS ID. Also, it is expected that the subjects will have a good speech understanding with the new fitting algorithm. This shall be proven by analyzing the aided free field hearing thresholds and aided speech discrimination scores post-operatively.
The third trial objective is to confirm the safety of the C-DACS ID in subjects with severe to profound mixed hearing loss. On the one hand this will be done by measuring and analyzing the bone conduction thresholds 3-months post-activation. On the other hand all surgical complications related to the

procedure and all post-operative complication related to the device will be analyzed and reported.

Study design

The clinical investigation is designed as a prospective, open, multi-center study in up to 10 patients.
Study centers are the Medizinische Hochschule Hannover (MHH) in Hanover/Germany and the UMC
St. Radboud in Nijmegen/The Netherlands.
The C-DACS ID will be implanted in combination with a traditional stapedotomy surgical procedure.

Intervention

A regular stapedotomy will be performed in combination with a mastoidectomy, a posterior tympanotomy and the placement of the experimental C-DACS ID device.

Study burden and risks

Burden
The participants will visit the clinic at least 5 times voor audiometric evaluation, activation and adjustement of the middle ear implant. After implantation by surgery a short stay at the ward is necessary.

Benefits
Subject benefits are anticipated to be:
· Improvement of hearing sensitivity
· Improvement of speech understanding
· Improvement of sound quality
· Improvement of quality of life
· No occlusion of ear canal

Risks
· Study subjects are exposed to the normal risks associated with surgery and general anaesthesia.
· Study subjects are exposed to the risks associated with standard stapes surgery.
· Study subjects are also exposed to the risks associated with standard mastoidectomy which
can cause additional risks like injury of the sigmoid sinus, jugular bulb, and dura; and
cerebrospinal fluid leakage.
·The C-DACS ID results in a palpable lump under the skin just behind the ear. Thiscause irritation, inflammation or breakdown of the skin and,
in some cases, extrusion of the device.

· Mechanical stimulation of the inner ear may result in temporary or permanent loss of hearing sensitivity or increased sensorineural hearing loss, increased tinnitus, dizziness or pain. The long term effect of mechanical stimulation of the cochlea is unknown.
· Failure of component parts (both external and internal) could result in the perception of an uncomfortably loud sound sensation, no sound or pain. Tissue damage could occur.
· Over-stimulation of the ear might occur, causing brief unpleasant sensations.
· The implanted device can cause inflammatory (allergic) reactions which might lead to medicaltreatment, hospitalization, and, in the worst case, removal of the device.
· External impact on a certain point on the head can cause the stapes prosthesis to move inwards, which might cause dizziness, pain, tinnitus, and, in the worst case, damage of inner or middle ear structures, which might lead to partial or complete loss of residual hearing.

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

1. Eighteen years of age or older
2. Mixed severe to profound hearing loss
3. Conductive hearing loss is a result of otosclerosis or prior failed stapes surgery
4. Bone conduction thresholds are worse than 40 dB HL on at least 3 out of 5 frequencies (500 Hz, 1 kHz, 2 kHz, 3 kHz and 4 kHz) but must be measurable at all five frequencies
5. Bone conduction thresholds equal to or greater than 30 dB HL in all frequencies
6. Air-bone gap equal to or greater than 30 dB HL on at least 3 out of 5 frequencies
7. Bone conduction of contra-lateral ear is equal to or worse than 30 dB HL at the best frequency

Exclusion criteria

1. Participation in another medical device study
2. Unwillingness or inability of the subject to comply with all study requirements
3. Bone conduction threshold exceeds 80 dB HL at 1 or more out of 5 frequencies (500 Hz, 1 kHz, 2 kHz, 3 kHz and 4 kHz)
4. Air conduction threshold exceeds 120 dB HL at 1 or more out of 5 frequencies (500 Hz, 1 kHz, 2 kHz, 3 kHz and 4 kHz)
5. Medical or psychological conditions that would contraindicate undergoing surgery
6. Sudden hearing loss
7. Disabling tinnitus
8. Insufficient mastoid and/or ear canal size (to be checked on CT scan)
9. Other criteria at investigator*s discretion

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-09-2010
Enrollment:	5
Type:	Actual

Ethics review

Approved WMO

Date:	29-09-2010
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	NL31992.091.10