Association Between Intra-Operative Cochlear Response Telemetry and Hearing Preservation.

Published: 22-02-2018
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To examine whether compromised cochlear microphonic (CM) response during cochlear implant surgery results in poorer acoustic hearing preservation compared to preserved CM.

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

Summary

ID

NL-OMON48826

Source
ToetsingOnline

Brief title
CREST study

Condition

- Hearing disorders

Synonym
cochlear monitoring, Cochleography

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Cochlear implantation, Cochlear Response Telemetry, electrocochleogram, monitoring

Outcome measures

Primary outcome

Deterioration in average low frequency post-operative hearing threshold levels (HTLs) at 4-6 weeks post-surgery in the implanted ear for subjects with compromised Cochear Microphonics (CM) compared to subjects with preserved CM during surgery.

Secondary outcome

1. Deterioration in average low frequency post-operative HTLs at 3 months post-activation in the implanted ear for subjects with compromised CM compared to subjects with preserved CM during surgery.

2. Association of pre-operative high frequency HTLs with onset of CM response during electrode array insertion.

3. Safety data in the form of adverse events where they occur.

Study description

Background summary

Significant advancements in implantable device technology and refinements to surgical technique have led to progressive improvement in the ability to preserve acoustic hearing after implantation. However, although hearing preservation has been demonstrated with a range of devices (Adunka et al. 2004; Gantz and Turner 2004; Gstoettner et al. 2009; Fraysse et al. 2006; Gantz et al. 2009; Lesinski-Schiedat et al. 2011; Lenarz et al. 2013; Lenarz et al. 2009; Skarzynski et al. 2010; Roland et al. 2016), it is not yet possible to guarantee for an individual candidate that acoustic hearing will be preserved. Although the cause of post-operative hearing loss is likely multifactorial,

events that occur during surgery are likely to be of influence. In order to understand the influence of such surgical factors, it is important to develop monitoring and diagnostic tools for use in the clinical setting, and to determine the specific intra-operative events that are associated with acoustic hearing loss. Furthermore, if reliable intra-operative tools were developed it may be possible to provide near real-time feedback to the surgeon as to change in acoustic hearing status during electrode insertion, and for the surgeon to modify or refine the surgical technique to minimize risk to loss of acoustic hearing.

Study objective

To examine whether compromised cochlear microphonic (CM) response during cochlear implant surgery results in poorer acoustic hearing preservation compared to preserved CM.

Study design

Prospective, multi-center, observational (non-randomized) investigation.

Study burden and risks

Participation in the trial requires time investment (four visits of about one hour each, which are part of the standard clinical procedure for cochlear implantation) and effort to complete routine measurements. The experimental Cochlear Response Telemetry measurements (electrocochleography) will be performed intra-operative and either 4-6 weeks post-operative or 3 months post-activation. It is anticipated that the additional time required to conduct the intra-operative measurement will be 10-15 minutes. The post-operative measurement will take approximately 30-60 minutes.

The risks associated with this investigational device are considered to be low.

There will be no benefit for the subject from participation in this research. However, it is possible that the information obtained from this study will assist in future to develop reliable tools to improve the cochlear implant surgery.

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

* Candidate for cochlear implantation according to local indications
* 18 years of age or older at the time of enrolment
* Pre-operative audiometric threshold in the implanted ear at 500 Hz of better than or equal to 80 dB HL
* Willingness to participate in and to comply with all requirements of the protocol

Exclusion criteria

* Prior cochlear implantation in the ear to be implanted
* Ossification or any other cochlear anomaly that might prevent complete insertion of the electrode array
* Abnormal cochlear/nerve anatomy on pre-operative CT or MRI imaging (excluding a mild Mondini malformation or Large Vestibular Aqueduct Syndrome)
* Deafness due to lesions of the acoustic nerve or central auditory pathway
* Diagnosis of auditory neuropathy
* Active middle-ear infection
* Additional handicaps that would prevent participation in evaluations

* Unrealistic expectations on the part of the subject, regarding the possible benefits, risks and limitations that are inherent to the procedure and investigational device

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-06-2018
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Cochlear Response Telemetry
Registration:	No

Ethics review

Approved WMO Date:	22-02-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	23-07-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	01-08-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	19-11-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-03-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	06-06-2019
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	07-11-2019
Application type:	Amendment
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
ClinicalTrials.gov	NCT03134989
CCMO	NL61426.091.17

Study results

Date completed:	01-05-2020
Actual enrolment:	15

Summary results
Trial ended prematurely