CART sound therapy for tinnitus relief in Nucleus® cochlear implant users with tinnitus

Published: 10-05-2017
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To quantify the tinnitus relief provided by CART sound therapy.

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

Summary

ID

NL-OMON46972

Source
ToetsingOnline

Brief title
CART study

Condition

- Hearing disorders

Synonym
ringing of the ear, Tinnitus

Research involving
Human

Sponsors and support

Primary sponsor: Cochlear AG, European Headquarters
Source(s) of monetary or material Support: Cochlear AG;European Headquarters

Intervention

Keyword: adult, cochlear implant, sound therapy, tinnitus

Outcome measures

Primary outcome

The main study parameters are the change in VAS-scores (Visual Analog Scale) on tinnitus loudness and annoyance and the change in the score on the Tinnitus Functional Index (TFI) between baseline and intervention.

Secondary outcome

Secondary parameters are the ratings on the acceptability of CART sounds, (Serious) Adverse Event reporting and speech perception tests with CART on and off.

Study description

Background summary

Sound enrichment therapy is a well-established therapy for patients suffering from tinnitus (Hoare et al, 2014, Sereda et al 2016). Studies show that electrical stimulation independent of environmental sounds provided via CI suppresses tinnitus significantly (Dauman et al., 1993; Rubinstein et al., 2003; Chang et al., 2010, 2012; Reavis et al., 2010, Zeng et al., 2011; Arts et al., 2015a, 2015b, 2016a, 2016b). Tyler and colleagues (2015) investigated the effect on tinnitus of background sound generated by a cable connected MP3 player and mixed with the microphone input of the CI. They reported on a series of case studies including six patients and concluded that mixed stimulation can be effective for suppressing tinnitus. The aim of this study is to investigate whether streaming of background sounds directly via the Sound Processor of the cochlear implant system making use of CART sound therapy can provide relief from tinnitus in cochlear implant users with tinnitus. The background sounds provided by CART are mixed with the signal picked up by the microphone of the CI to assure accurate environmental sound and speech perception during background stimulation.

Study objective

To quantify the tinnitus relief provided by CART sound therapy.

Study design

Prospective, exploratory, repeated measures clinical trial.

Intervention

CART sound therapy.

Study burden and risks

This study consists of two phases. The expected duration of phase 1 is about 2 hours after which the participants will have the opportunity to move on to phase 2. The expected duration of phase 2 is about 7 weeks, including two visits to the clinic. All visits will last about two hours. Subjects are advised to use CART sound therapy continuously during the day, but they are free to change the volume. During the study patient diaries and questionnaires must be completed and one speech perception test will be performed. All CART sounds will be applied using the standard CI remaining well within its conventional clinical safety limits. Therefore, the risks associated with participation is estimated to be low.

The potential benefit of participation is that participants become aware of sound therapy through the CI in general. This can help to gain better control of the tinnitus after participation in the study. It is expected that the CART algorithm will increase users* comfort compared to sound enrichment generated by a cable connected MP3 player. Moreover less battery consumption is expected compared to wireless streaming via commercially available sound enrichment tools.

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

Self-reported tinnitus during standard cochlear implant use.

Exclusion criteria

History of psychiatric disorders or depression (on investigator*s opinion).

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-10-2017

Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Cochlear Active Relief from Tinnitus (software application integrated in CE-marked cochlear implant
Registration:	No

Ethics review

Approved WMO Date:	10-05-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-07-2017
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-03-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NCT03026829
CCMO	NL58657.068.17

Study results

Date completed:	24-01-2019
Actual enrolment:	32

Summary results
Trial ended prematurely