Perceptual evaluation of changes in sound quality after surgically changing the shape of the osseous external auditory canal.

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Primary Objective: The present study is designed to answer the question whether the surgically altered OEAC leads to a perceived change in sound quality.Secondary Objective(s): To determine the differences in RECD and REUR induced by different OEAC...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	External ear disorders (excl congenital)
Study type	Observational non invasive

Summary

ID

NL-OMON40771

Source
ToetsingOnline

Brief title
Changes in sound quality after surgically changing the OEAC

Condition

- External ear disorders (excl congenital)

Synonym
ear canal surgery, ear surgery

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: ear canal acoustics, ear canal surgery, preference, RECD

Outcome measures

Primary outcome

The main study parameter is the subjective preference for the sound quality,

measured by paired comparison category rating and a VAS.

Secondary outcome

-

Study description

Background summary

In individual cases, patients have reported a subjective improvement of sound quality after surgical alteration of the osseous external auditory canal (OEAC). To our knowledge, there are no studies on the effect of a change in the external ear acoustic properties on perceived sound quality. The present study aims to investigate the subjective sound quality of a surgically changed OEAC by using sound simulations of surgically altered ears and present these conditions to two both the hearing impaired subjects and normal hearing listeners.

Study objective

Primary Objective:

The present study is designed to answer the question whether the surgically altered OEAC leads to a perceived change in sound quality.

Secondary Objective(s):

To determine the differences in RECD and REUR induced by different OEAC surgery procedures such as mastoïdectomy, obliteration of an open cavity, exostose, etcetera.

Study design

This study is an observational study including subjects with surgically altered OEAC, and a panel of normal hearing listeners. The different outer ear canal acoustics are simulated using filtering based on both the REUR and the RECD of the surgically altered OEACs of the hearing impaired subjects. These simulations of the different OEAC conditions facilitate a perceptive evaluation in both the hearing impaired subjects using the RECD and an insert earphone, and in the normal hearing listeners using the REUR in a free field setting. During one visit, ranging from 0.5 to 2 hours, the hearing capacity and external ear acoustic properties are characterized using standard clinical tests (i.e. pure tone audiometry, the in situ measurement of the REUR and RECD, and tympanometry). In addition, a subjective comparison category rating is included to determine the individual preferences in sound quality in terms of naturalness, sharpness, and etcetera. A VAS score is used to determine the subjective overall sound quality.

Study burden and risks

Since this study is observational, the burden for the patients is minimal. Several tests similar or equal to those done in standard clinical practice will be done during one visit. The primary outcome of the study aims to provide more information about the effects of OEAC surgery on the subjective perception of sound. This is relevant for patients who need to undergo an otological operation in which the OEAC acoustics will be altered, in addition to the medical considerations.

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

- Aged 18 years or older.
- Sufficient knowledge of the Dutch language, both spoken and written, in order to being able to participate in the perceptual evaluation experiment.
- Hearing impaired subjects:
o Uni- or bilateral surgically altered OEAC
o pure tone hearing thresholds of 70 dB(HL) or better for all audiometric frequencies between 250 and 8000 Hz in the ear(s) with the altered OEAC.
- Normal hearing listeners:
o Pure tone hearing thresholds of 20 dB(HL) or better for all audiometric frequencies between 250 and 8000 Hz.
o no history of ear infection nor any ear surgery.

Exclusion criteria

- Pure tone hearing thresholds do not meet the specified criteria.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial

Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-10-2014
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	19-05-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL48271.018.14

Study results

Results posted: 19-10-2017

Summary results
Trial ended prematurely

First publication
19-10-2017