Perceptual evaluation of changes in sound quality after mastoidectomy: open cavity mastoid versus obliterated mastoid cavity.

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

Summary

ID

NL-OMON50662

Source
ToetsingOnline

Brief title
Changes in sound quality after mastoidectomy

Condition

- External ear disorders (excl congenital)

Synonym
ear surgery, mastoidectomy

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, mastoidectomy, preference, RECD

Outcome measures

Primary outcome

The main study parameter is the subjective preference of the subjects for the

sound quality as perceived by a normal ear canal versus an open cavity mastoid,

and by a normal ear canal versus an obliterated mastoid cavity.

Secondary outcome

-

Study description

Background summary

In individual cases, patients have reported a change in the subjective sound quality after mastoidectomy or after obliteration of the mastoid cavity. These changes in sound quality depend on the acoustical properties of the outer ear. The acoustical properties can be characterized by standard clinical procedures as the measurement of the Real Ear Unaided Response (REUR) and the Real Ear to Coupler Difference (RECD). The hypothesis is that the ear canal acoustical properties and the subjective sound quality mainly depend on the total volume of the ear canal and the additional volume of a mastoid cavity. Since an obliteration of the mastoid cavity more or less restores the original volume of the outer ear canal, the procedure of obliteration should be able to restore the subjective quality of sound.

Study objective

The primary objective of this study is to answer the question whether the obliteration of an open cavity mastoid restores the subjective sound quality as perceived in the particular ear. The secondary objective is to determine the differences in RECD and REUR between normal ears, ears with open cavity mastoids and ears with obliterated mastoid cavities.

Study design

An observational study including two groups of subjects, one with unilateral open cavity mastoids and one with unilateral obliterated mastoid cavities. By simulation of the different outer ear canal acoustics using the inter aural differences in RECD, a double blind investigation of the subjects preferences in sound quality can be performed in both the normal ear as in the pathological ear. During one visit of about 2.5 hours, the hearing capacity and external ear acoustic properties are characterized using standard clinical tests. In addition, a subjective comparison category rating is included to determine the individual preferences in 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 give more information about the effects of the obliteration of open cavity mastoid ears on the subjective perception of sound. This is relevant for patients who consider to undergo an obliteration of an open cavity mastoid, 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.
- Single sided open cavity mastoid, or a single sided obliterated mastoid, with pure tone hearing thresholds of 70 dB(HL) or better for all audiometric frequencies between 250 and 8000 Hz.
- Normal external ear properties in the contralateral ear, with no history of middle ear or mastoid surgery, and pure tone hearing thresholds of 20 dB(HL) or better for all audiometric frequencies between 250 and 8000 Hz.
- Sufficient knowledge of the Dutch language, both spoken and written, in order to being able to participate in the perceptual evaluation experiment.

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):	09-06-2013
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	24-01-2013
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	NL42243.018.12