Feasibility of middle ear OCT imaging

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To assess the feasibility and the clinical potential of structural and functional OCT imaging with Aurisvue in patients with various middle ear problems.

Ethical review	Approved WMO
Status	Pending
Health condition type	Middle ear disorders (excl congenital)
Study type	Observational invasive

Summary

ID

NL-OMON51754

Source
ToetsingOnline

Brief title
Feasibility of middle ear OCT imaging

Condition

- Middle ear disorders (excl congenital)

Synonym
ear infections, Middle ear diseases, otitis media

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Acoustic Insight B.V.

Intervention

Keyword: Diagnostic Imaging, Middle ear, OCT

Outcome measures

Primary outcome

Percentage of patients in which structural OCT imaging was feasible (i.e., the OCT images showed a discernible tympanic membrane (TM) and at least one of the ossicles).

Secondary outcome

- Number of middle ear structures (TM, ossicles) on which OCT-vibrometry measurements by Aurisvue succeeded.

- For diagnostic correlation with other clinical data sources (only as far as they are available from the standard of care):

o microscopic otoscopy (description)

o CT-scan

o MRI-scan

o pure-tone audiogram

o tympanogram

o surgical report (if available)

Study description

Background summary

Various middle ear diseases can affect anatomical structures of the middle ear in different ways. Unfortunately, current methods for assessing the structure and function of the constituents of the middle ear are limited and often fail to provide all clinically relevant data. Optical coherence tomography (OCT) is a technology that can provide valuable, additional information. Aurisvue is a newly developed prototype OCT-device for structural and functional imaging of the middle ear.

Study objective

To assess the feasibility and the clinical potential of structural and functional OCT imaging with Aurisvue in patients with various middle ear problems.

Study design

Observational study.

Study burden and risks

The examination time is estimated at 10 minutes. The research is expected to be minimally burdensome because the technology is not invasive.
The risks are estimated as very limited.

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

Suspected middle ear problem

Exclusion criteria

Any acute or chronic condition that would limit the ability of the patient to participate in the study, per attending physician*s indication, including:
o Abnormally narrow or stenotic external meatus (ear canal)
o Movement disorder causing inability to keep head still during imaging

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	24-10-2022
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Generic name:	AurisVue
Registration:	No

Ethics review

Approved WMO Date:	25-11-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL81519.078.22