Cholesteatoma disease recidivism after canal wall up tympanomastoidectomy with or without obliteration: a randomized controlled trial (CLEAR-EAR).

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

Summary

ID

NL-OMON57358

Source
ToetsingOnline

Brief title
CLEAR-EAR

Condition

- Middle ear disorders (excl congenital)

Synonym
abnormal, noncancerous growth of skin cells that forms behind the eardrum

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

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

Intervention

Keyword: Canal wall up, Cholesteatoma, Disease recurrence, Hearing

Outcome measures

Primary outcome

Rates of recurrent or residual cholesteatoma are evaluated by diffusion-weighted magnetic resonance imaging (DW-MRI) and micro-otoscopy after approximately one, three and five years. If diffusion restriction is seen on DW-MRI and/or retraction of the tympanic membrane is seen during micro-otoscopy, suspicion for recurrent or residual disease will be recorded. To confirm the diagnosis and to determine whether the cholesteatoma is either recurrent or residual, we will analyse the tympanic membrane description at the beginning of the revision surgery.

Secondary outcome

All other surgical outcome measures are recorded in the surgical report. Pure tone audiograms, including air and bone conduction, and speech recognition scores are evaluated pre- and postoperatively for each patient. The EQ-5D-5L, HUI-3, iMCQ and iPCQ questionnaires will be filled in once pre- and a two times postoperatively by every patient. The OQUA will be filled in once preoperatively and three times postoperatively. The direct health-care costs will be recorded for the sponsor centre and extrapolated for the whole trial.

Study description

Background summary

The mainstay of cholesteatoma treatment is surgery with effective and safe removal of the disease as the principal goal. New techniques find their way in the international otologic community by proving lower recurrent and residual disease rates compared to the conventional techniques. One newly implemented and previously described technique is the obliteration technique of the mastoid and epitympanum. Although this approach has become more popular in recent years, high-quality evidence is missing.

Study objective

The primary aim of this study is to investigate whether a canal wall up (CWU) tympanomastoidectomy with obliteration of the mastoid and paratympanic or epitympanic spaces reduces cholesteatoma recurrence and residual rates compared to the same approach without obliteration. Secondarily, hearing outcomes after both surgical techniques are compared to investigate whether one of the two results in superior postoperative hearing. The quality of life will be measured using the Otology Questionnaire Amsterdam (OQUA). The economic evaluation will involve collecting the intervention costs from the sponsoring centre and extrapolating them to the entire trial.

Study design

The proposed study is a single-blind randomized controlled trial. Patients are randomized into one of two groups in an equal 1:1 allocation ratio. The randomization will be centre-stratified and a 4,6,8 block randomization will be used.

Study burden and risks

The burden patients will experience by participating in this study will be filling in the questionnaire multiple times. The surgery, along with the imaging procedures (CT and DW-MRI), audiometry and follow-up appointments, is part of standard care and takes place irrespective of participation in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
- The patient is willing to participate and has provided written informed consent authorization before participating in the study
- The patient is >=18 years of age at the time of consent
- The patient has sufficient understanding of the Dutch written language
- The health status of the patient allows general anaesthesia and surgery for the removal of a cholesteatoma
- The patient is eligible to undergo a CWU tympanomastoidectomy approach based on the clinical and/or radiological suspicion for a cholesteatoma. Patients should only be included when the surgeon deems a transcanal approach not feasible and that, therefore, a mastoidectomy is necessary based on the pre-operative assessment.
- The patient is covered by a health insurance company

Exclusion criteria

- Cases of revision surgery due to residual disease with a normal, intact or reconstructed tympanic membrane
- Cases where a previous obliteration has taken place

- Cases of congenital cholesteatoma
- Patient with an indication for the surgery due to a disease other than cholesteatoma (chronic otitis media)
- In rare cases patients may have a pathology which makes obliteration unavoidable due to the invasiveness of the disease (e.g. cholesteatoma extension into and near total destruction of the bony ear canal or bony tegmen plate). This is judged by the treating physician.
- Severe comorbidity with an expected survival of less than five years
- Comorbidity or disorder which could interfere with the completion of questionnaires (e.g. known psychiatric disorder, mental retardation)
- Compromising anatomical situation (i.e. radical cavity, Congenital craniofacial anomalies with involvement of the temporal bone and including cleft palate)
- Contraindication to undergo a diffusion-weighted magnetic resonance imaging (DW-MRI) (e.g. claustrophobic, metal parts of implants in the body such as a pacemaker)

Study design

Design

Study type: Observational non invasive

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2025
Enrollment:	106
Type:	Anticipated

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	13-03-2025
Application type:	First submission
Review commission:	METC NedMec

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	NL86362.041.24