Cost effectiveness of follow-up with diffusion-weighted MRI versus surgical follow-up after cholesteatoma treatment.

Published: 20-03-2017
Last updated: 20-04-2024

OBJECTIVE(S)/RESEARCH QUESTION(S) 1. Are the hearing levels after three years of follow-up with annual diffusion-weighted MRI comparable to those after follow-up with second look surgery?2. Is a diffusion-weighted MRI follow-up strategy cost-...

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

Summary

ID

NL-OMON47835

Source
ToetsingOnline

Brief title
Cost effectiveness of MRI diffusion in cholesteatoma follow-up

Condition

- Middle ear disorders (excl congenital)

Synonym
cholesteatoma, middle ear sac of skin

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Stichting Het Heinsius-Houbolt Fonds

Intervention

Keyword: Cholesteatoma, Cost-effectiveness, Hearing, MRI diffusion

Outcome measures

Primary outcome

OUTCOME MEASURES

1. The degree of hearing loss after 3 thee years of follow-up

Secondary outcome

2. The costs of three years follow-up

3. The number of 2nd look surgeries without cholesteatoma present (unnecessary

surgical procedures)and the number of residual and recurrent cholesteatoma,

health related quality of life and number of complications

Study description

Background summary

BACKGROUND
Eradication and follow-up of a cholesteatoma (a keratine mass in the ear) is mandatory because it is a slow growing but destructive disease with the risk of hearing loss, imbalance or facial nerve paralysis. Follow-up must be done because in about 20% there is a residual cholesteatoma.

Study objective

OBJECTIVE(S)/RESEARCH QUESTION(S)
1. Are the hearing levels after three years of follow-up with annual diffusion-weighted MRI comparable to those after follow-up with second look surgery?
2. Is a diffusion-weighted MRI follow-up strategy cost-effective compared to second look surgery?
3.Are other outcome measures (residual and recurrent cholesteatoma, quality of life and adverse events) comparable between both follow-up strategies?

Study design

STUDY DESIGN
Economic evaluation alongside a prospective multicenter randomized controlled trial with an intention-to-treat analysis plus additional observational study.

Intervention

INTERVENTION
Annual diffusion-weighted MRI during 3 consecutive years, starting 1 year after primary surgery.

STANDARD INTERVENTION TO BE COMPARED TO
Second look surgery 1 year after primary surgery and follow-up during 3 consecutive years.

Study burden and risks

Only questionnaires will be extra for all patients
Half of the patients will undergo the standard care, which is a tympanoplasty/ second look surgery including one day hospitalization.
The other half will undergo each year a MRI scan of around 40 minutes
There are NO additional interventions which are part of the research, they are all part of the normal follow-up (like audiogram, otoscopy)

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Inclusion criteria RCT
* 18 years of age or older.
* patients who underwent a surgical procedure (canal wall up tympanoplasty) for eradication of primary or recurrent acquired cholesteatoma
* primary surgery at a maximum of 11 months prior to the start of the study.
* patients with normal to mild conductive hearing loss, defined as:
mean air-bone gap of less than or equal to (*) 20dB on pure tone audiometry at frequencies of 0.5, 1 and 2 kHz .
* capable and willing to participate in a follow-up study of three years

Exclusion criteria

* patients who underwent a canal wall down tympanoplasty procedure as last ear surgical procedure (patients with a canal wall down procedure in the last 10 months will be requested to participate in the cholesteatoma observational study, which is an anonymous follow-up study of usual care in post-cholesteatoma surgery patients without randomization);* patients with a moderate to severe average air-bone gap of more than (>) 20 dB (patients eligible for a chain reconstruction will be requested to participate in the cholesteatoma observational study);* patients not capable to undergo a MRI (claustrophobic, metal parts or implants in the body etc.)

Study design

Design

Study type:	Observational invasive
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-05-2017
Enrollment:	153
Type:	Actual

Ethics review

Approved WMO Date:	20-03-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-06-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-05-2019
Application type:	Amendment
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	NL50862.029.16
Other	NTR application pending