Cost effectiveness of MRI diffusion in cholesteatoma follow-up

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Diffusion-weighted MRI is a cost-effective follow-up strategy after primary cholesteatoma surgery compared to the usual care, 2nd look surgery with equal quality of care in terms of hearing, cholesteatoma detection rate, complications and quality of...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26889

Bron
Nationaal Trial Register

Verkorte titel
DCD

Aandoening

ENG: Cholesteatoma, MRI, Hearing, Cost-effectiveness, Quality of Life, QALY

DUTCH: Cholesteatoom, MRI, Gehoor, Kosteneffectiviteit, Kwaliteit van Leven, QALY

Ondersteuning

Primaire sponsor: Vrije Universiteit Medisch Centrum
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. The degree of hearing loss (in average air-bone gap (dB))and high and low Fletcher index in each year of follow-up after primary cholesteatoma surgery

Toelichting onderzoek

Achtergrond van het onderzoek

BACKGROUND

Eradication and follow-up of a cholesteatoma (a keratin 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.

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?

HYPOTHESIS

Diffusion-weighted MRI is a cost-effective follow-up strategy after primary cholesteatoma surgery compared to the usual care, 2nd look surgery with equal quality of care in terms of hearing, cholesteatoma detection rate, complications and quality of life.

STUDY DESIGN

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

STUDY POPULATION(S)/DATASETS

153 patients of 16 years and older after primary or recurrent cholesteatoma surgery treatment with normal to mild conductive hearing loss.

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.

OUTCOME MEASURES

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

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

SAMPLE SIZE CALCULATION/DATA ANALYSIS

To detect a clinically relevant difference of 8dB conductive hearing loss, the minimal number of participants needed after 3 year follow-up is: 122 (61 in each arm). Because of an expected drop-out of 20%, 153 patients will be included..

COST-EFFECTIVENESS ANALYSIS/ BUDGET IMPACT ANALYSIS

An economic evaluation will be performed from a societal as well as a healthcare perspective

Intervention costs of surgery and MRI will be estimated using a micro-costing approach.

Both a cost-effectiveness analysis in terms of the primary outcome (hearing) and a cost-utility analysis (QALYs) will be performed. Economic evaluations will be performed in accordance with the intention-to-threat principle

TIME SCHEDULE (months)

0-12 inclusion of participants

6-18 first intervention

30 two year follow-up and 85% of all interventions completed

34-48 start implementation, national and local meetings and guideline group

44-48 completion of the data gathering, analysis and publication

KEYWORDS

Cholesteatoma, MRI, Hearing, Cost-effectiveness, Quality of Life, QALY

Doel van het onderzoek

Diffusion-weighted MRI is a cost-effective follow-up strategy after primary cholesteatoma surgery compared to the usual care, 2nd look surgery with equal quality of care in terms of hearing, cholesteatoma detection rate, complications and quality of life.

Onderzoeksopzet

TIME SCHEDULE (months)

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Onderzoeksproduct en/of interventie

Only questionnaires will be extra for all patients
Half of the patients will undergo the standard care, which is a second look surgery intervention 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)

Contactpersonen

Publiek

Vrije Universiteit Medisch Centrum - Afd. KNO

Paul Merkus
PO Box 7057

Amsterdam 1007 MB
The Netherlands
020-4443690

Wetenschappelijk

Vrije Universiteit Medisch Centrum - Afd. KNO

Paul Merkus
PO Box 7057

Amsterdam 1007 MB
The Netherlands
020-4443690

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 16 years of age or older.

• patients who underwent a surgical procedure (canal wall up tympanoplasty) for eradication of primary acquired or recurrent 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 or 1,2 and 4 kHz.

• capable and willing to participate in a follow-up study of three years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• 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)

• 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.)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2016
Aantal proefpersonen:	153
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort: Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5899
NTR-old	NTR6087
Ander register	ZonMw project: 80-83700-98-16504 : ABR/CCMO: NL50862.___.16

Resultaten