EDB for Ménière's disease

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20715

Source
Nationaal Trial Register

Brief title
EDB trial

Health condition

Ménière's disease

Sponsors and support

Primary sponsor: HagaHospital, The Hague
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

Proportion of patients free of vertigo attack at 12 months follow up

Secondary outcome

Secondary outcomes are defined as minimally clinically significant differences in
- cumulative incidence of vertigo bouts
- hearing

- use of escape medication
- co-interventions
- complications of surgery
- questionnaire outcomes (FLS, DHI, THI, SF-36, EQ-5D VAS, iPCQ, iMCQ)
- CEA
- BIA
- endolymphatic hydrops on MRI
- physiotherapeutical outcomes

Study description

Background summary

Ménière’s disease (MD) is an incapacitating disease in which recurrent attacks of vertigo are accompanied by hearing loss, tinnitus and/or aural fullness. Current treatments have either proven to be ineffective (Betahistin), destroy the labyrinth function (intratympanic gentamicin and ablative surgery) or only provide a temporary solution (intratympanic corticosteroid injections). Recently, a new, surgical technique has been published by Saliba et al. This technique, referred to as Endolymphatic Duct Blockage (EDB), involves blocking the connection of the endolymphatic sac with the inner ear by clipping the endolymphatic duct (ED). A previous study reported very favourable results of EDB, but this study was methodologically flawed, as it was not blinded. Therefore, this trial is performed to to evaluate the effectiveness of surgical clipping of the ED in participants with Ménière’s disease, as compared to a decompression surgery without clipping.
84 participants will be randomised into the EDB-arm of the decompression surgery trial. Both the follow up ENT-surgeon and the patient will be blinded. Participants from both study groups will undergo mastoidectomy with identification of the ED. In the EDB group, the ED will be clipped and in the decompression group, it will not be clipped. All participants receive vestibular rehabilitation after surgery. Follow up visits will take place at 1 week, 3 months, 6 months and 12 months after surgery.

Study objective

We hypothesize that the number of patients without vertigo spells at 12 months follow up will be higher in the group that has undergone EDB than in the decompression group.

Study design

>4 week before inclusion, 1 week after surgery, 3 months after surgery, 6 months after surgery, 12 months after follow up, 12 months after surgery of last patient.

Intervention

Participants from both study groups will undergo mastoidectomy with identification of the ED.

In the EDB group, the ED will be clipped and in the decompression group, it will not be clipped. All participants receive vestibular rehabilitation after surgery. Follow up visits will take place at 1 week, 3 months, 6 months and 12 months after surgery.

Contacts

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Eligibility criteria

Inclusion criteria

- Definite unilateral MD according to diagnostic criteria of the Bárány Society (Lopez-Escamez, 2016)
- More than 3 patient reported attacks in the 6 months prior to inclusion and at least 1 attack in the 2 months prior to inclusion
- Age ≥ 18 years at the start of the trial
- Non responding to a sufficient extent to conservative medical treatment including at least two sessions of at least one intra-tympanic injection (IT) each with corticosteroids (dexamethasone, methylprednisolone, triamcinolonacetonide)
- Dutch health care insurance

Exclusion criteria

- Severe disability (e.g. neurological, orthopedic, cardiovascular) according to the investigator, pregnancy or serious concurrent illness that might interfere with surgery or follow-up.
- Active additional neuro-otologic disorders that may mimic MD (e.g. vestibular migraine (VM), recurrent vestibulopathy, phobic postural vertigo, vertebro-basilar TIAs, acoustic neuroma, congenital disorders, enlarged vestibular aquaduct (EVA)-like or genetic disorders (like DFNA9), cervicogenic dizziness), based on the complete clinical record.

- Previous ear surgery for MD (IT injection is not an exclusion criterion)
- Language difficulties
- Active otitis media (with or without effusion)
- Unable or unwilling to use DizzyQuest App
- Unable to undergo MRI (such as gadolinium allergy, claustrophobia, implanted non-MRI compatible device of material, BMI)
- Deafness of the contralateral ear

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2021
Enrollment:	84
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
All data will be published in an appropriate journal. It is expected that it will take about 6 months after completion of follow up of the last patient for the results to be submitted.

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL9095
Other	METC Leiden Den Haag Delft : P20.118

Study results