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Ear (endolymphatic) duct blockage as a treatment for unmanageable Meniere's disease

Submission date 31/12/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 24/02/2021	**Overall study status** Completed	
Last Edited 18/11/2025	**Condition category** Ear, Nose and Throat	

Plain English summary of protocol

Background and study aims

Ménière's disease (MD) is a condition of the inner ear that causes sudden attacks of: feeling like the room is spinning around you (vertigo); a ringing noise inside the ear (tinnitus); pressure felt deep inside the ear; hearing loss.

A population of 60 -100 per 100,000 in the Netherlands have a low quality of life due to the disease. Current treatments have either proven to be ineffective or only provide a temporary solution. Recently, a new, surgical technique has been developed, known as Endolymphatic Duct Blockage (EDB).

The objective of this study is to evaluate the effectiveness of surgical clipping of the ED in participants with Ménière's disease, as compared to a decompression surgery without clipping.

Who can participate?

Patients with Meniere's disease that is not responsive to more conservative treatment will participate in this trial. Participants are from the Netherlands.

What does the study involve?

Participants from both study groups will undergo mastoidectomy (a surgical procedure that removes diseased mastoid cells) with the identification of the endolymphatic duct (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. Patients will additionally have MRI scans, hearing test and vestbular function tests.

What are the possible benefits and risks of participating?

Benefits for the participants in this study are that 50% of the participants will undergo EDB surgery of which we believe (based on the previously discussed results of EDB) that it will effectively treat their vertigo attacks. Of the participants in the decompression group, an estimated 70% will benefit from a placebo effect. Therefore, only 30% of the sham group (n = 13, 15% of the total study population) will not directly benefit from participation in the study. Furthermore, if at the end of the study these participants would still be eligible for EDB surgery

and results are in favour of the EDB procedure, EDB surgery can be performed in less time with less trauma and risk, since the access to the ED through the petrous bone has already been established during the decompression operation.

Where is the study run from?
Haga Hospital (The Netherlands)

When is the study starting and how long is it expected to run for?
August 2020 to November 2024

Who is funding the study?
The Dutch Healthcare Institute (Zorginstituut Nederland)

Who is the main contact?
Annejet Schenck, duizeligheid@hagaziekenhuis.nl

Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NL9095

Study information

Scientific Title

The effectiveness of endolymphatic duct blockage versus endolymphatic sac decompression in patients with intractable Ménière's disease

Study objectives
Current study hypothesis as of 26/04/2021:
The number of patients free of vertigo attacks at 12 months after surgery is ≥25% higher in the EDB group than in the decompression group.

Previous study hypothesis:
The number of patients free of vertigo attacks at 12 months after surgery is ≥25% higher in the EDB group than in the control group'

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 19/03/2021, MREC Leiden The Hague Delft (room P5-22, P.O. box 9600, Leiden, 2300 RC, Netherlands; +31 71 526 3241; metc-ldd@lumc.nl), ref: P20.118vp

Study design
Prospective multicentre randomized double-blinded parallel-group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Meniere's disease

Interventions
Current interventions as of 24/04/2023:
74 patients will be randomised using a computer to either the EDB group or the decompression group.
Patients in both groups undergo mastoidectomy and identification of the endolymphatic duct. In the EDB group, the duct is then clipped using a titanium clip. This clip is not placed in the decompression group.

Both patient and the follow-up researcher are blinded to treatment allocation.

Surgery will take several hours +1 day hospital stay. All participants will be followed up for 1 year after their surgery. All patients undergo vestibular rehabilitation therapy after surgery.

Previous interventions as of 26/04/2021:
84 patients will be randomised using a computer to either the EDB group or the decompression group.
Patients in both groups undergo mastoidectomy and identification of the endolymphatic duct. In the EDB group, the duct is then clipped using a titanium clip. This clip is not placed in the decompression group.

Both patient and the follow-up researcher are blinded to treatment allocation.

Surgery will take several hours +1 day hospital stay. All participants will be followed up for 1 year after their surgery. All patients undergo vestibular rehabilitation therapy after surgery.

Previous interventions:
84 patients will be randomised using a computer to either the EDB group or the control group. Patients in both groups undergo mastoidectomy and identification of the endolymphatic duct. In the EDB group, the duct is then clipped using a titanium clip. This clip is not placed in the control group.

Both patient and the follow-up researcher are blinded to treatment allocation.

Surgery will take several hours +1 day hospital stay. All participants will be followed up for 1 year after their surgery. All patients undergo vestibular rehabilitation therapy after surgery.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Vertigo attacks in past 12 months measured through a daily app-based questionnaire, starting from the day of inclusion until 1 year of follow up

Key secondary outcome(s))
1. Number of vertigo bouts measured using a daily app-based questionnaire, starting from the day of inclusion until 1 year of follow up
2. Hearing measured using audiometry at baseline, 3, 6 and 12 months follow up
3. Use of escape medication (including intratympanic injections) will be recorded at the follow up visits at 1 week, 3, 6 and 12 months follow up
4. Co-interventions (ablative procedure) will be recorded at the follow up visits at 1 week, 3, 6 and 12 months follow up
5. Complications of surgery as extracted from the patients record
6. Functional level scale is measured using the FLS questionnaire at baseline, 3, 6 and 12 months follow up
7. Dizziness is measured through the Dizziness Handicap Inventory (DHI) at baseline, 3, 6 and 12 months follow up
8. Tinnitus is measured using the Tinnitus Handicap Inventory (THI) at baseline, 3, 6 and 12 months follow up
9. General health measured using SF-36 at baseline, 3, 6 and 12 months follow up
10. Cost-effectiveness is measured using the productivity cost questionnaire (iPCQ), the medical cost questionnaire (iMCQ) at baseline, 3, 6 and 12 months follow up
11. Endolmyphatic hydrops will be measuring using MRI scan at baseline, 3 and 12 months follow up
12. Balance will be measured using a Romberg, a sharpened Romberg, One Leg Stance Test at baseline and 3, 6 and 12 months post operatively
13. Gait will be assessed using the Dynamic Gait Index (DGI) at baseline and 3, 6 and 12 months post operatively
14. Dynamic visual acuity will be measured using the Dynamic Visual Acuity TEST (DVAT-NI) at baseline and 3, 6 and 12 months post operatively

Completion date

03/11/2024

Eligibility

Key inclusion criteria
1. Definite unilateral MD according to diagnostic criteria of the Bárány Society (Lopez-Escamez, 2016)
2. 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
3. Age ≥18 years at the start of the trial
4. 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)
5. Dutch health care insurance

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
75

Key exclusion criteria
Current participant exclusion criteria as of 26/04/2021:
1. Severe disability (e.g. neurological, orthopedic, cardiovascular) according to the investigator, pregnancy or serious concurrent illness that might interfere with surgery or follow-up
2. 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
3. Previous ear surgery for MD (IT injection is not an exclusion criterion)
4. Language difficulties
5. Active otitis media (with or without effusion)
6. Unable or unwilling to use DizzyQuest App

7. Unable to undergo MRI (such as gadolinium allergy, claustrophobia, implanted non-MRI compatible device of material, BMI)
8. Deafness of the contralateral ear

Previous participant exclusion criteria:
1. Severe disability (e.g. neurological, orthopedic, cardiovascular) according to the investigator, pregnancy or serious concurrent illness that might interfere with surgery or follow-up
2. 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
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5. Active otitis media (with or without effusion)
6. Unable or unwilling to use DizzyQuest App
7. Unable to undergo MRI (such as gadolinium allergy, claustrophobia, implanted non-MRI compatible device of material, BMI)

Date of first enrolment
01/06/2021

Date of final enrolment
12/09/2023

Locations

Countries of recruitment
Netherlands

Study participating centre
Haga Hospital
Els Borst-Eilersplein 275
The Hague
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2545 AA

Sponsor information

Organisation
Haga Hospital

ROR
https://ror.org/03q4p1y48

Funder(s)

Funder type
Government

Funder Name
Zorginstituut Nederland

Alternative Name(s)
National Health Care Institute, ZIN

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	10/08/2021	12/08/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes