

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

Submission date 31/12/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 24/02/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/01/2024	Condition category Ear, Nose and Throat	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

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 vestibular 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

Study website

<http://www.hagaziekenhuis.nl/meniere>

Contact information

Type(s)

Public

Contact name

Miss Annejet Schenck

ORCID ID

<http://orcid.org/0000-0002-3093-175X>

Contact details

Haga Hospital

Els Borst-Eilersplein 275

The Hague

Netherlands

2545 AA

+31 620280814

duizeligheid@hagaziekenhuis.nl

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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 $\geq 25\%$ 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 $\geq 25\%$ 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

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

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 measure

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

Secondary outcome measures

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. Endolymphatic 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

Overall study start date

01/08/2020

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, triamcinolonacetone)
5. Dutch health care insurance

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

74

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
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)

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

Netherlands

2545 AA

Sponsor information

Organisation

Haga Hospital

Sponsor details

Els Borst-Eilersplein 275

The Hague

Netherlands

2545AA

+31 702100000

kno@hagaziekenhuis.nl

Sponsor type

Hospital/treatment centre

Website

<http://www.hagaziekenhuis.nl>

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

Publication and dissemination plan

Each article or abstract will be submitted according to the authors' guideline as predefined by the journal. Before submitting, the supervising researchers will recommend changes to the authors. A pre-submission English-language editing will be performed. The articles following from this project will be submitted to the appropriate high-impact peer-reviewed journals,.

Intention to publish date

01/05/2025

Individual participant data (IPD) sharing plan

The current data sharing plans for this study are unknown and will be available at a later date.

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