EDB for Ménière's disease

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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.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20715

Bron
Nationaal Trial Register

Verkorte titel
EDB trial

Aandoening

Ménière's disease

Ondersteuning

Primaire sponsor: HagaHospital, The Hague
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

>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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2021
Aantal proefpersonen:	84
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
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.

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	NL9095
Ander register	METC Leiden Den Haag Delft : P20.118

Resultaten