Onderzoek naar chirurgische ingreep bij ziekte van Ménière van start

1. Deelnemende centra
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2. Inclusiecriteria
- Definitieve, unilateral Menière volgens de diagnostische criteria van de Bárány Society (Lopez-Escamez, 2016)
- Meer dan 3 patiëntgerapporteerde aanvallen in de 6 maanden voorafgaand aan inclusie, waarvan minimaal 1 in de laatste 2 maanden voor inclusie
- >18 jaar op het moment van inclusie
- Niet in voldoende mate reagerend op meer conservatieve behandeling, waaronder minimaal 2 sessie van intratympanale injecties met corticosteroiden (dexamethason, methylprednisolon, triamcinolonacetonide)
- Nederlandse zorgverzekering

3. Exclusiecriteria
- Comorbiditeit, zwangerschap of andere ziekte die mogelijk interfereert met de operatie of follow up volgens de zorgverlener
- Actieve bijkomende neuro-otologische ziekten die lijken op Meniere (zoals vestibulaire migraine, vestibulopathie, TIA's)
- Eerdere oorchirurgie voor Meniere (intratympanale injecties vallen hier niet onder)
- Taalproblemen/-barrière
- Actieve otitis media (met of zonder effusie)
- Niet in staat of niet bereid DizzyQuest App te gebruiken
- Niet in staat MRI met contrast te ondergaan (gadolinium allergie, claustrofobie, metaal in lichaam)
- Doofheid aan het contralaterale oor

Samenvatting (Engels)

Rationale: Ménière's disease (MD) is an incapacitating disease in which recurrent attacks of vertigo are accompanied by hearing loss, tinnitus and/or aural fullness. A population of 60-100 per 100.000 patients in the Netherlands is severely impaired (low quality of life) by the disease. 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). In many countries, surgery on the endolymphatic sac, such as decompression, shunting or drainage, is part of standard care

for Meniere's disease, but not in the Netherlands and Scandinavian countries. 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 paradigm shift for the pathophysiological model of Ménière's disease underlies this new treatment. Patients with MD have a hydrops of the endolymphatic system as can be demonstrated by MRI (3 Tesla). Until now, it is believed that the surplus of endolymph causing the hydrops originates in the cochlea and the vestibular organ. However, Saliba et al. state that the surplus of endolymph originates in the endolymphatic sac (ES) and that Ménière's disease originates from the ES as well. Saliba et al. report very favourable results of EDB, but their study was methodologically flawed, as it was not blinded. Therefore, we feel obliged to perform a so-called pivotal trial to establish whether EDB is more effective than endolymphatic sac decompression for controlling vertigo in patients suffering from MD.

Objective: 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 the decompression procedure where the duct is not clipped. We expect that the number of patients free of vertigo attacks at 12-months postoperative will be higher in the EDB group than in the decompression group. In addition, we hypothesize that there will be less hearing loss, tinnitus, loss of vestibular function and hydrops, and an increase in quality of life (QoL) in participants in the EDB group.

Study design: This is a double-blinded, randomized controlled trial. Total duration of the study is 4 years. Minimal study duration per participant is 1-year post surgery. All of the operations will take place in participating centres within a fixed period of 2 years after the first patient is operated. Surgery will be performed by two surgeons simultaneously. One of the surgeons will leave the operating room before the randomisation. This surgeon is blinded to the treatment and will take care of the follow-up. Randomization will be 1:1 stratified for gender and duration of MD (recent onset versus mature MD).

Study population: The study will include 84 participants suffering from MD who meet the diagnostic criteria as recently revised in 2015. These patients have not responded to more conservative treatment modalities.

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.

Main study endpoint: Proportion of patients who are free of vertigo spells at 12 months post-operative.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: All participants will have ear surgery, repeated testing and questionnaires and report daily in the DizzyQuest app. Usual risks of surgery apply. We expect patients in both groups to benefit from participation, either because of the effect of the surgical interventions, or because of the considerable placebo effect.

An interim analysis will be performed after 21 participants have undergone surgery to assess surgery related risks and to end the trial if safety of participants cannot be guaranteed.