

The Effectiveness of Intratympanic Methylprednisolon Injections Compared to Placebo in the Treatment of Vertigo Attacks in Meniere's Disease

NCT05851508

Status	RECRUITING
Phase	Phase 3
Sponsor	Leiden University Medical Center
Enrollment	148 participants

Key Eligibility Criteria

Inclusion (5)

- Unilateral, definite MD according to the diagnostic criteria derived from the American Academy Otolaryngology Head and Neck Surgery, Classification Committee of the Bárány Society, European Academy of Otolology and Neurotology and International Classification of Vestibular Disorders published in 2015 [7] (see Appendix 1):
- Definite MD Two or more spontaneous episodes of vertigo, each lasting 20 minutes to 12 hours, AND Audiometrically documented low- to medium-frequency sensorineural hearing loss in one ear, defining the affected ear on at least one occasion before, during or after one of the episodes of vertigo, AND Fluctuating aural symptoms (hearing, tinnitus, or fullness) in affected ear (not better accounted for by another vestibular diagnosis)
- age > 18 years at the start of the trial.
- e 4 vertigo attacks over the last 6 months.
- willing to adhere to daily trial medications and the follow-up assessments.

Exclusion (8)

- A potential subject who meets any of the following criteria will be excluded:
- bilateral MD
- severe disability (e.g. neurological, orthopaedic, cardiovascular) or serious concurrent illness that might interfere with treatment or follow-up.
- active additional neuro-otologic disorders that may mimic MD (e.g. vestibular migraine, recurrent vestibulopathy, phobic postural vertigo, vertebro-basilar TIAs, acoustic neuroma).
- otitis media with effusion based on tympanogram results.
- ... and 3 more (see full listing online)

Locations (1 total)

Leiden University Medical Centre, Leiden, South Holland, Netherlands