The effect of a high dose compared to a low dose of betahistine in the treatment of vertigo attacks in Menière's disease

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27414

Source
NTR

Brief title
BETMEN trial

Health condition

Menière's disease, betahistine, randomised controlled trial

Sponsors and support

Primary sponsor: Prof. Dr. P.P.G. van Benthem (November 2015)
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Intervention

Outcome measures

Primary outcome

Complete control of vertigo or reduction in vertigo attack frequence related to the dose of betahistine.

Secondary outcome

1.Frequency of co-interventions including: use of escape medication (metoclopramide) and intratympanic injections (dexamethason or gentamicin).

2. Change in pure tone audiometry scores.

3. Change in Functional Level Scale scores.

4. Change in Dizziness Handicap Index scores.

5. Change in Tinnitus Handicap Index scores.

6. Change in Multifrequency Tympanometry scores (Y width).

7. Frequency of adverse events.

Study description

Background summary

The effect of betahistine on vertigo attacks in patients with Meniere’s Disease (MD) has been investigated in several placebo-controlled randomized cross-over and parallel designed trials. Generally the authors concluded betahistine reduced vertigo attack frequency. A Cochrane review investigating this matter stated that due to the lack of high quality studies its clinical efficacy remains inconclusive. However, recent publications claim the existence of a dose-related effect of betahistine which needs to be further elucidated. As betahistine is registered as the only long-term treatment for MD patients in the Netherlands, performing a placebo-controlled trial would be unethical. Therefore, performing a dose-finding study is essential to clarify if a high dose betahistine (48 mg three times per day, tid) is superior to low dose betahistine (8 mg tid) in reducing the frequency of vertigo attacks in patients diagnosed MD.

Study objective

High dose betahistine (48 mg three times per day, tid) is superior to low dose betahistine (8 mg tid) in reducing the frequency of vertigo attacks in patients diagnosed with definite unilateral MD.

Intervention

Betahistine 48 mg three times per day or betahistine 8 mg three times per day.

Contacts

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Eligibility criteria

Inclusion criteria

1. Unilateral MD (definite or probable) according to diagnostic criteria derived from the American Academy Otolaryngology Head and Neck Surgery, Classification Committee of the Bárány Society, European Academy of Otology and Neurotology and International Classification of Vestibular Disorders published in 2015.

2. Age > 18 years at the start of the trial.

3. ≥ 4 vertigo attacks over the last 6 months.

4. Willing to adhere to daily trial medication and the follow-up assessments.

Exclusion criteria

1.Bilateral MD.

2.Severe disability (e.g. neurological, orthopedic, cardiovascular) or serious concurrent illness that might interfere with treatment or follow-up.

3. Active additional neuro-otologic disorders that may mimic MD (e.g. vestibular migraine, recurrent vestibulopathy, phobic postural vertigo, vertebro-basilar TIAs, acoustic neuroma).

4. Otitis media with effusion or perforation of the eardrum based on tympanogram results.

5. Contraindication for usage of betahistine e.g. known pheochromocytoma, bronchial asthma or allergy to this agent.

6. History of intratympanic injections with corticosteroids, gentamicin or ear surgery for treating MD.

7. Use of other antihistaminic agents or MAO inhibitors.

8. Women of child bearing age not using contraception, pregnant women or nursing women.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-12-2016
Enrollment:	74
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5263
NTR-old	NTR5379
Other	: GELRE.ADC.BETMEN.2015.

Study results

Summary results
Not applicable