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

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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.

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

Samenvatting

ID

NL-OMON27414

Bron
NTR

Verkorte titel
BETMEN trial

Aandoening

Menière's disease, betahistine, randomised controlled trial

Ondersteuning

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2016
Aantal proefpersonen:	74
Type:	Verwachte startdatum

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	NL5263
NTR-old	NTR5379
Ander register	: GELRE.ADC.BETMEN.2015.

Resultaten

Samenvatting resultaten
Not applicable