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Medical treatment of Meniere's disease with betahistine: a placebo-controlled, dose-finding study

Submission date	Recruitment status	[X] Prospectively registered
10/08/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/01/2016	Ear, Nose and Throat	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
04T-617

Study information

Scientific Title

Medical treatment of Meniere's disease with betahistine: a placebo-controlled, dose-finding study

Acronym
BEMED

Study objectives
High-dose betahistin (3 x 48 mg per day) is more effective in reducing the number of vertigo attacks in Meniere's disease than low-dose betahistin (3 x 24 mg) or placebo.
As of 20/12/2011, target number of participants and anticipated end date have been modified.
Previous target number of participants: 84
Previous anticipated end date: 31/10/2010

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the local medical ethics board on the 2nd February 2008.

Study design
Placebo-controlled, double-blind, randomised controlled trial.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Meniere's disease

Interventions
Please note that the first patient was randomised in April 2008.

The trial comprises three arms:
1. Therapy with high-dose betahistine (3 x 48 mg)
2. Therapy with low-dose betahistine (2 x 24 mg)
3. Placebo

The total treatment time will be nine months with a three month follow-up. The trial is estimated to last three years (first patient in to last patient out).

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Betahistin

Primary outcome(s)
Number of vertigo attacks in the three treatment arms during the last three months of the treatment period.

Key secondary outcome(s))
1. Number of vertigo attacks during the last three months of the total follow-up period
2. Median duration of vertigo attacks and median severity of vertigo attacks during the last three months of the treatment period and the last three months of the total follow-up period
3. Change of:
3.1. Peripheral vestibular function
3.2. Tinnitus intensity
3.3. Effect of tinnitus on quality of life
3.4. Subjective hearing loss
3.5. Objective hearing loss - determined by acoustic evoked potentials
3.6. Change of handicap/impairment due to vertigo or dizziness - assessed by the Dizziness Handicap Inventory (DHI) and the Vestibular Disorders Activities of Daily Living (VADL) score
Between baseline, nine-month and 12-month follow-up visit

Completion date
30/01/2012

Eligibility

Key inclusion criteria
1. Definite Meniere's disease according to the American Academy of Ophthalmology and Otolaryngology, Head and Neck Surgery:
1.1. Two or more attacks of vertigo, each lasting more than 20 minutes
1.2. Audiometrically documented hearing loss in at least one examination
1.3. Tinnitus or aural fullness in the affected ear
1.4. Other causes excluded
2. At least two attacks of Meniere's disease per month for at least three subsequent months
3. Aged 18 to 80 years
4. Written informed consent to all protocol-specified procedures

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
All

Key exclusion criteria
1. Other vestibular disorders such as vestibular migraine or phobic postural vertigo
2. Contraindications for treatment with betahistine-dihydrochloride, such as:
2.1. Asthma bronchiale

2.2. Pheochromacytoma
2.3. Pregnancy or breast-feeding
2.4. Severe dysfunction of kidneys or liver
2.5. Ulcer of the stomach or duodenum
2.6. Tumours
2.7. Severe coronary heart disease
2.8. Treatment with other antihistamines

Date of first enrolment
01/11/2007

Date of final enrolment
30/01/2012

Locations

Countries of recruitment
Germany

Study participating centre
Klinikum Grosshadern
Munich
Germany
81377

Sponsor information

Organisation
University Hospital Grosshadern (Klinikum Grosshadern) (Germany) - Department of Neurology

ROR
https://ror.org/02jet3w32

Funder(s)

Funder type
Government

Funder Name
German Federal Ministry of Education and Research (Bundesministerium Fur Bildung und Forschung [BMBF]) (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	21/01/2016		Yes	No