The effect of the Meniett in patients with unstable Meniere's disease

Published: 25-03-2008
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Evaluation of the effect of treatment with the Meniett in patients with unstable Menière*s disease.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Interventional

Summary

ID

NL-OMON31493

Source
ToetsingOnline

Brief title
Meniett puls therapy in Menière's disease

Condition

- Inner ear and VIIIth cranial nerve disorders

Synonym
Dizziness spells, Vertigo spells

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: low pressure pulse therapie, Menière□s disease, Meniett

Outcome measures

Primary outcome

frequency of the vertigo spells

Secondary outcome

duration of vertigo spells

functionality level scale

Dizziness Handicap Inventory

Hearing thresholds

Study description

Background summary

Menière*s disease is a disorder characterized by recurrent vertigo spells, tinnitus and loss of hearing. These symptoms have a major impact on daily life and severely reduce quality of life. Especially the recurrent vertigo spells are disabling. The cause of Menière*s disease is unknown. However, there are indications that the underlying pathology is endolymfatic hydrops, which is an increase of endolymfatic fluid in the scala media of the cochlea.
At present no effective therapy is available. The current treatment of Menière*s disease is aimed at reducing the endolymfatic hydrops.(diuretics, salt restriction etc)
Animal studies suggest a hydrops can be reduced by applying positive pulse pressure therapy to the inner ear. Based on these results a device, called the Meniett was designed to produce positive pulse pressure waves.
Various clinical trials with the Meniett have been preformed, unfortunatly with varying results. None of these trials have focused on the effect of the Meniett in unstable Meniere disease. Theoretically, early treatment of unstable Meniere's disease, before definite damage to the inner ear has occured,could stop disease progression.

Study objective

Evaluation of the effect of treatment with the Meniett in patients with

unstable Menière*s disease.

Study design

A randomized dubbel-blind, placebo-controlled prospective cross-over study

Intervention

A tympanic tube will be inserted in all subject under lokal anesthesia. Two weeks after insertion of the tympanic tube treatment will start. After randomisation half of the patients will start the treatment with the Meniett, half of the patients will start with the placebo.
Patients will use the Meniett for at least five minutes three times a day or more frequently wit a maximum of 10 times a day if so desired. Patients will be treated for 12 weeks with the Meniett or placebo and after a 2 week interval cross over to the other treatment arm. There will be a 2 week follow-up period after the treatment is ended.

Study burden and risks

The main risk in this study is formed by insertion of the tympanic tube. Insertion of a tympanic tube is concidered a routine procedure in the ENT practice. Some studies have suggested a positive effect of the tube insertion in Menière*s disease. However conclusive proof has not been provided. Treatment with the meniett device is a safe and non-invasive. Previous studies with the Meniett have shown that no adverse events are to be expected. This specific patient group continously requests attention from clinical professionals, but hardly ever gets it. Therefore participants in this sudy will probably not consider their participation in this study as a burden.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

defenite Menière acoording to the AAO-HNS:
two or more vertigo spells >20 minutes
audiometrically documented hearing loss at at least one occasion
Tinnitus or aural fullness in the treated ear
Other auses excluded
2. Instable Menière*s disease:
at least 3 vertigo spells en/or fluctuating hearing loss in the three months prior to inclusion

Exclusion criteria

controlateral pathology of the ear
ipsilateral pathology of the middle ear
chirurgic treatment for Menière*s disease

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-08-2009
Enrollment:	32
Type:	Actual

Medical products/devices used

Generic name:	Meniett low pressure pulse generator
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	25-03-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL16864.041.07