*Efficacy and safety of intratympanic dexamethasone compared to intratympanic gentamicin in patients with proven unilateral Ménière*s disease*; a randomised, double-blind, controlled non-inferiority trial

Published: 10-12-2013
Last updated: 24-04-2024

To compare the effect of IT dexamethasone versus IT gentamicin on number and severity vertigo attacks.To compare the effects of IT dexamethasone with IT gentamicin on hearing function, functional level scale and aural fullness.

Ethical review	Not approved
Status	Will not start
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Interventional

Summary

ID

NL-OMON40458

Source
ToetsingOnline

Brief title
DEXAvsGENTA trial

Condition

- Inner ear and VIIIth cranial nerve disorders

Synonym
Meniere's disease, Morbus Meniere

Research involving

Human

Sponsors and support

Primary sponsor: Gelre Ziekenhuizen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: dexamethasone, gentamicin, Meniere, vertigo

Outcome measures

Primary outcome

We expect a 20% risk difference between the two treatments. A non*inferiority design will be applied with a 10% inferiority margin. If the lower value of the confidence interval of the risk difference is more than 10%, dexamethason will be concluded to be inferior to gentamicin.

Secondary outcome

Other endpoints are 12 points decrease in Dizziness Handicap Inventory (DHI) score, Tinnitus Handicap Inventory (THI), Pure Tone Audiometry, Speech Discrimination scores, Level of total hearing loss.

Study description

Background summary

There is no established treatment for Ménière's disease, nor agreement on whether Ménière's disease is a single clinical entity or an umbrella syndrome covering different aetiologies and pathophysiological mechanisms. Lately, IT treatments have been advocated and IT gentamicin injections have been established for refractory attacks of vertigo in Ménière's disease.
This treatment however carries an inherent risk of aggravating the hearing loss and alternatives have been sought. Of these, local treatment with steroids has shown to be promising in that no hearing deterioration is expected and indeed some studies report improvement in hearing.

Study objective

To compare the effect of IT dexamethasone versus IT gentamicin on number and severity vertigo attacks.
To compare the effects of IT dexamethasone with IT gentamicin on hearing function, functional level scale and aural fullness.

Study design

Randomised, double-blind, controlled, non-inferiority multicenter study

Intervention

Dexamethasone (20 mg/ml) 0,5 * 0,6 ml or gentamicin (40 mg/ ml) 0.5 ml * 0,6 ml.
Patients receive two injections within two weeks.

Study burden and risks

Patients will visit the hospital five times for study purposes.
The treatment phase will be two weeks and the follow-up phase will be 24 months after the last IT injection.
Follow up visits will be performed at six months, 12 months and 24 months.
During participation there will be several safety tests.
In both treatment groups, there is a small chance of pain, short-lasting vertigo, otitis media, and membrane perforation after intratympanic injection.
There is a risk of hearing loss with gentamicin therapy.
The potential advantage of intratympanic steroid therapy is the beneficial effect on hearing when compared to gentamicin therapy.
Following the risk classification scheme of the Nederlandse Federatie van Universitair Medische Centra (NFU) the risk for participation in this trial is negligible.
The safety risk for patients in both groups is the same as in normal clinical practice. For IT gentamicin the risk hearing loss of ca. 20%, but even during the use of dexamethasone, there is a possibility of hearing loss due to the natural course of M. Ménière. It is unpredictable in which patient hearing loss will occur.
In both groups there is a risk of ineffectiveness of vertigo control and a small risk of infection, temporary pain, discomfort.
The risk and burden for the subjects is in proportion to the potential value of the research.
At this moment there are no unknown risks.

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

*Definite unilateral Ménière's disease according to AAO-HNS criteria: two or more definitive spontaneous episodes of vertigo for at least 20 minutes, AND audiometric confirmation of a sensorineural hearing loss, AND tinnitus (other causes excluded)
*Not responding to oral medical treatment for at least six months.
*Age above 18 years at the start of the trial.
*Willing to adhere to the follow up assessments.

Exclusion criteria

*Ménière's disease in advanced stages (not having vertigo attacks).
*bilateral Ménière's disease.

*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 Ménière's disease (e.g. vestibular migraine, vertebro-basilar TIAs, acoustic neuroma).
*Concurrent ear pathology that may interfere with IT injections (e.g. active middle ear disease).
*Family history of unexplained deafness (possibility of genetic susceptibility to gentamicin toxicity).
*History of known adverse and/or allergic reaction to steroids or gentamicin.
*Women of child bearing age not using contraception, pregnant women or nursing women.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	66
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	dexamethasone
Generic name:	dexamethasone
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	gentamicin

Generic name:	gentamicin
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	10-12-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Not approved Date:	16-06-2014
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
EudraCT	EUCTR2013-004086-14-NL
CCMO	NL46537.041.13