Vestibulotoxicity in consequence of tobramycin therapy in cystic fibrosis patients

Published: 30-10-2006
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Primary objective: to investigate the prevalence of vestibulotoxicity and disturbance of equilibrium as far a Cystic Fibrosis patients with at least one treatment with tobramycin are concerned. Secondary objective: To formulate an advice for...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Inner ear and VIIIth cranial nerve disorders
Study type	Observational invasive

Summary

ID

NL-OMON29992

Source
ToetsingOnline

Brief title
vestibulotoxicity in cystic fibrosis patients

Condition

- Inner ear and VIIIth cranial nerve disorders

Synonym
damage of the inner ear, disturbance of equilibrium

Research involving
Human

Sponsors and support

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

Intervention

Keyword: aminoglycoside, cystic fibrosis, tobramycin, vestibulotoxicity

Outcome measures

Primary outcome

Primary study parameter is formulated as whether there is damage to the

vestibulum or there is not.

Secondary outcome

Secundary study parameter is formulated as whether there is disturbance of

equilibrium due to damage of the vestibulum or there is not.

Study description

Background summary

Most of the CF patients were treated with repeated therapies of tobramycine. Known and described are the cochleo-, vestibulo- and nephrotoxicity of aminoglycoside, of which cochleotoxicity is familiar in clinical practice. CF patients, like other patients with repeated therapy with aminoglycoside, are being screened by pure tone audiometry. Research concerning vestibulotoxicty in vivo, particularly in humans, is not established yet, with the exception of some case reports.
This study is purposed to investigate the vestibulotoxicity due to aminoglycoside with a clinical approach. Because CF patients are repeatedly treated with aminoglycosides as well as frequently screened for hearing loss, they form an interesting research population.

Our hypothesis is that CF patients with repeated tobramycin therapy do have an elevated risk on vestibulotoxicity, and, therefore, has to be screened on vestibular function in addition to screening for cochleotoxicity

Study objective

Primary objective:
to investigate the prevalence of vestibulotoxicity and disturbance of equilibrium as far a Cystic Fibrosis patients with at least one treatment with tobramycin are concerned.

Secondary objective:
To formulate an advice for possible screening for vestibulotoxicity with Cystic Fibrosis patients with at least one treatment with tobramycin are concerned.

Study design

Observational cohort study

Study burden and risks

The burden associated with participation is concerned with an ENG investigation (45 min.).
Preceding, the patient is asked to complete a questionnaire (5 min.) and the patient will be seen by an independent ENT doctor. This doctor will have a look using the microscope to exclude patients with perforation in the tympanic membrane and will do a ordinary physical examination as far as the equilibrium is concerned (10 min.).
All investigations are minimal invasive and none of them can harm the patient.

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

cystic fibrosis patients currently known in the HAGA hospital who have been treated at least one time with intravenous tobramycin and with an audiogram in medical dossier

Exclusion criteria

patients treated with other intravenous aminoglycoside therapy than tobramycine
patients receiving intravenous aminoglycosides during investigation.
patients with perforation of one of the tympanic membranes.
patients with a radical cave.

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2006
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	30-10-2006
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL13333.098.06