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Otosclerosis is an isolated ear disorder which can cause hearing and balance impairment. The cause of these symptoms is a disturbed bone metabolism confined to the area of the otic pit, the embryologic predecessor of the inner ear. Most patients...

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

Samenvatting

Bron

NTR

Aandoening

Onderwerp:

- Keel-, neus- en oorheelkunde
- Otosclerose (fenestraal en cochleolabyrinthair)
- PET/CT-beeldvorming

Subject:

- Otorhinolaryngology
- Otosclerosis (fenestral and cochlear)
- PET/CT imaging

Ondersteuning

Primaire sponsor :

INITIATOR:
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Overige ondersteuning : Not yet acquired.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Semiquantitative measurements (SUV) of patients and control subjects at different areas of interest.

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

Otosclerosis is an isolated ear disorder which can cause hearing and balance impairment. The cause of these symptoms is a disturbed bone metabolism confined to the area of the otic pit, the embryologic predecessor of the inner ear. Most patients present with fenestral otosclerosis, in which there is otosclerosis in the area around the oval window (causing fixation of the stapes foot plate and therefore conductive hearing loss). If otosclerosis advances it can progress to the inner ear (cochlear otosclerosis), causing sensorineural hearing loss and balance problems.

The result of the disturbed bone metabolism causes otospongiosis, which can be visualised on computed tomography (CT). The aim of this study is to assess the degree of disease activity (as a derivative of bone metabolism) with ^{18}F -fluoride PET. ^{18}F -fluoride is a tracer used uniquely for bone imaging purposes.

The hypothesis is that patients with otosclerosis have a higher uptake of ^{18}F -fluoride in the area of interest than control patients. Control patients underwent a ^{18}F -fluoride PET/CT for various other, mainly orthopaedic, reasons.

Onderzoeksopzet

Otosclerosis is a disorder with a very indolent course (years). This is the reason that the PET

scan and the high resolution CT scan (for regular medical treatment) are not necessarily performed on the same date.

Different specific areas can be affected by otosclerosis:

1. Fenestral area (oval window area, close to stapes);
2. Bone adjacent to medial aspect of the cochlea;
3. Bone adjacent to lateral aspect of the cochlea;
4. Bone adjacent to apex of the cochlea;
5. Anterior wall of the internal auditory canal;
6. Posterior wall of the internal auditory canal;
7. Bone adjacent to lateral aspect of the semicircular canals.

Assessment of the PET scans: Standard Uptake Values (SUV) at different areas in the inner ear.

Assessment of the CT scans: Bone density measurements (Hounsfield Units) of the same areas.

Assessment of the audiometric data:

1. (Progression of the) conductive hearing loss;
2. (Progression of the) sensorineural hearing loss.

Onderzoeksproduct en/of interventie

30 otosclerosis patients: 18F-fluoride PET scan of the head and neck with a low-dose CT scan for attenuation. Apart from that patients will undergo, or may already have undergone, a high-resolution CT scan as part of their regular medical treatment.

10 patients with fenestral otosclerosis, 10 patients with moderate cochlear otosclerosis, 10 patients with severe cochlear otosclerosis.

10 control patients: 18F-fluoride PET/CT scan (for other, mainly orthopaedic indications) in which the head and neck area is included.

Control patients are not specifically appointed to the study but will be selected retrospectively. The scanning protocol is the same for both control patients and otosclerosis patients.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Study patients:

1. Fenestral otosclerosis;
2. Cochlear otosclerosis.

Control patients:

1. Clinically relevant reason to undergo a PET/CT-scan with 18F-fluoride, in which the head & neck region is scanned as part of the protocol.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Otosclerosis patients:

1. Prior ear surgery at the concerning ear;
2. Chronic otitis media or chronic mastoiditis;
3. Tympanosclerosis diagnosed at prior ear surgery;
4. Claustrophobia or the inability to lie still during the scan;
5. Active malignancy;
6. Generalised bone condition (except osteoporosis);
7. Pregnancy or lactation.

Control patients:

1. A history of ear surgery, with the exception of tympanic tubes;
2. Otosclerosis;
3. Generalised bone condition (except osteoporosis).

Onderzoeksopzet

Opzet

Type :	Interventie onderzoek
Onderzoeksmodel :	Parallel
Toewijzing :	Niet-gerandomiseerd
Blinding :	Open / niet geblindeerd
Controle :	Geneesmiddel

Deelname

Nederland	
Status :	Werving nog niet gestart
(Verwachte) startdatum :	01-01-2011
Aantal proefpersonen :	40
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	NL2465
NTR-old	NTR2581

Register

Ander register
ISRCTN

ID

METC MUMC : 10-2-028
ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A