Use of a PET scan to quantify disease activity in patients with hearing loss due to otosclerosis.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21643

Source
NTR

Health condition

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

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

Sponsors and support

Primary sponsor: INITIATOR:
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Source(s) of monetary or material Support: Not yet acquired.

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Disease activity compared to degree and course of hearing loss;

2. Disease activity compared to computed tomography findings.

Study description

Background summary

N/A

Study objective

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 18F-fluoride PET. 18F-fluoride is a tracer used uniquely for bone imaging purposes.

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

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2011
Enrollment:	40
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL2465
NTR-old	NTR2581
Other	METC MUMC : 10-2-028
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A