18F-fluoride PET-scan as complementary diagnostic medium for patients with otosclerosis - A pilot study

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To measure the 18F-fluoride activity of otosclerosis in patients diagnosed with otosclerosis (by audiometry, CT scan and/or operative findings) in a different stage of their disease. If this diagnostic proves to be reliable and reproducible, this...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Ear and labyrinthine disorders congenital
Study type	Interventional

Summary

ID

NL-OMON36729

Source
ToetsingOnline

Brief title
18F-fluoride PET-scan for otosclerosis

Condition

- Ear and labyrinthine disorders congenital
- Middle ear disorders (excl congenital)

Synonym
fixation of the stapes, otosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: 18F-fluoride, otosclerosis, PET-scan

Outcome measures

Primary outcome

Primary study paramater:

To demonstrate that the 18F-fluoride PET scan has an additional value in the diagnostic process in patients with otosclerosis.

Other research questions:

1. Is the bone metabolism in patients with otosclerosis in the area of interest (inner ear) higher than in individuals without this disorder?

Outcome measure: Standard Uptake Value (SUV)

2. Is there a correlation between the abnormalities found on CT scan and the abnormalities found on PET scan?

3. Can the PET scan predict the course of the process of otosclerosis/otospongiosis in an individual patient?

Secondary outcome

4. Is there a correlation between the bone activity measured with PET scan and the perioperative findings?

Study description

Background summary

Otosclerosis is diagnosed in many patients based upon the clinical symptomatology and the audiologic examination. A high-resoluiton CT scan can confirm the diagnosis. Until now only static diagnostics have played a role. Static diagnostics exhibit the damage caused by otosclerosis until the moment of the test. In certain cases there is a need for a dynamic diagnostic. With a dynamic diagnostic the activity of the disease can be investigated and the future hearing damage can be more accurately predicted. Other dynamic diagnostics have been proposed in the past, without success due to different reasons.

Study objective

To measure the 18F-fluoride activity of otosclerosis in patients diagnosed with otosclerosis (by audiometry, CT scan and/or operative findings) in a different stage of their disease. If this diagnostic proves to be reliable and reproducible, this can be of important value in the process of planning surgery or conventional hearing revalidation.

Study design

Observational patient-control study in which 3 groups of 10 patients with confirmed otosclerosis undergo a 18F-fluoride PET/CT scan. The control group consists of 10 individuals without an otologic history. 10 control patients will be selected that have undergone a similar scan for other diagnostic reasons.

Intervention

Patient population: PET/CT scan with 18F-fluorine. The tracer is administered by means of an intravenous injection. After one hour the actual PET/CT scan is performed. This is combined with a diagnostic CT scan of the skull base and a low-dose CT scan for attenuation.

Control subjects: no intervention. This group is selected retrospectively for analysis.

Study burden and risks

Radiation:

- 18F-fluoride scan: 5.4 mSv
- diagnostic CT scan of the inner ear area: 0.3 mv (patients only)
- attenuation low-dose CT scan of the head: 0.5 mSv (all individuals)

Compared to the average annual background radiation in the Netherlands: 2.0 mSv

Injection:

- possible redness or haematoma
- risk of phlebitis or lymphangitis

Logistic burden:

- PET scan is more time consuming than the conventional CT scan, around 2 hours.

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

Otosclerosis patients:
* fenestral otosclerosis
* cochlear otosclerosis;Control patients:
* Clinically relevant reason to undergo a PET/CT-scan with 18F-fluorine, in which the head & neck region is scanned as part of the protocol. The indication for the scan will be set by the nuclear specialist and the referring specialist.

Exclusion criteria

Otosclerosis patients:
* Prior ear surgery at the concerning ear
* Chronic otitis media or chronic mastoiditis
* Tympanosclerosis diagnosed at previous ear surgery
* Claustrophobia or the inability to lie still during the scan
* Active malignancy
* Generalised bone condition (except osteoporosis)
* Pregnancy or lactation
* Patient refuses to be notified about additional findings on the PET-scan;Control patients:
* A history of ear surgery, with the exception of ear grommets

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40

Type:	Anticipated

Ethics review

Approved WMO Date:	14-02-2011
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL31709.068.10