Fusion of Cardiac Computed Tomography Angiography (CTA) and 18F-Fluorodesoxyglucose Positron Emission Tomography (FDG-PET) to Determine Normal Peri-annular FDG Uptake after Aortic Valve Implantation

Published: 02-04-2013
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To determine normal FDG-uptake around PHV*s in aortic position.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac valve disorders
Study type	Observational invasive

Summary

ID

NL-OMON43910

Source
ToetsingOnline

Brief title
PROSPECTA

Condition

- Cardiac valve disorders

Synonym
endocarditis, prosthetic heart valve

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Aortic Prosthetic Heart Valve, Computed Tomography Angiography, endocarditis, Fluorodesoxyglucose/Posotron Emission Tomography

Outcome measures

Primary outcome

18F-FDG/PET baseline uptake measured by the QVSH value and the SUV ratio*s

around the PHV in early, late and possibly also in the chronic postoperative

phase: 5 (± 1) weeks, 12 (± 2) weeks and 12 (± 2) months respectively.

Secondary outcome

- Feasibility of hybrid fusion (diagnostic CTA and PET): percentage of

patients for which it is possible to fuse FDG-PET images and cardiac CTA

images

- Artefacts (region, extend and type and location) during assessment with

FDG-PET/CTA will be described

Study description

Background summary

Prosthetic Heart Valve (PHV) endocarditis is complicated by peri-annular extension (abscesses/mycotic aneurysms) in up to 50% of patients and has an in-hospital mortality of approximately 30%. However, with current standard imaging tools such as Echocardiography and Computed Tomography Angiography (CTA), it remains difficult to detect peri-annular extension, which is an indication for urgent surgery in order to reduce mortality. Furthermore, if

peri-annular abnormalities are found with imaging, differentiation between active and non-active inflammatory tissue is impossible, because of the lack of metabolic information. Hybrid imaging with combined anatomical information by CTA and metabolic information by FDG-PET may provide this additional information. However, normal baseline FDG uptake at different time points after aortic PHV implantation is unknown and obligatory for correct interpretation of CTA/PET scans in PHV patients.

Study objective

To determine normal FDG-uptake around PHV*s in aortic position.

Study design

Prospective multicentre cross-sectional study.
Included patients receive one 18-F FDG-PET/CTA after implantation of a PHV in aortic position. There is no control group or follow-up. Only 18-F FDG-PET/CTA results will be used for data analysis.

Study burden and risks

Risk: Prospectively ECG-triggered CTA and FDG-PET exposes the patient to a combined maximum radiation dose of 10.0 milli Sievert (mSv) which is approximately 4-5 times the annual natural background radiation. The risk of contrast-induced nephropathy (CIN) is minimal because of exclusion of patients with diminished renal function. In addition the risk of contrast media induced severe acute general reactions is 0.04% per patient. Co-incidental findings with FDG-PET and CTA are reduced to a minimum, because only the region of the heart/aortic root with PHV is scanned. In case of a co-incidental finding patients are informed and if needed further investigation is offered
Benefit: Asymptomatic postoperative PHV dysfunction may be detected in an early stage. Ascertaining the normal pattern of metabolic activity with FDG-PET surrounding PHVs will be of added value in the future evaluation of individual patients in this study and possibly for all FDG-PET studies performed worldwide on other patients with PHVs.

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

- age > 50 years
- patients after uncomplicated PHV implantation
- Normal routine follow-up TTE
- 5 weeks or 12 weeks or 12 months after PHV implantation
- weight < 110 kg

Exclusion criteria

- Known contrast allergy
- Known renal impairment (GFR<60)
- Other contraindications for contrast use according the standard daily clinical routine
- Use of pericardial patches and re-operation of aortic PHV in past medical history
- Contraindication for Computed Tomography Angiography according the standard daily clinical routine

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-05-2013
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO Date:	02-04-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-01-2017
Application type:	Amendment
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
CCMO	NL42743.041.12
Other	nnb