Fusie van cardiale CT en PET scan voor bepalen van normale glucose (suiker) opname rondom een Aorta Kunstklep

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24441

Source
NTR

Brief title
PROSPECTA

Health condition

PET-CT, CTA, prosthetic heart valve, endocarditis

Sponsors and support

Primary sponsor: University Medical Center Utrecht, Erasmus Medical Center Rotterdam
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

- Qualification Visual Score for Hypermetabolism (QVSH)

- Standardized Uptake Value (SUV) ratio (quantitative measurement)

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

Rationale:
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.

Objective: To determine normal FDG-uptake around PHV's in aortic position.

Study design: Prospective multi-centre cross-sectional study

Methods: 18-Fluorine FDG-PET is performed to assess uptake around the PHV after fusion with the CTA. FDG uptake is scored by: 1. Qualification Visual Score for Hypermetabolism (QVSH) which can be: none, mild, moderate or severe. 2. Standardized Uptake Value (SUV) ratio's, defined as the maximum SUV value around the PHV divided by the mean SUV value in the mediastinum.

Study population: The total group consists of patients (≥ 50 years) after uncomplicated PHV implantation in aortic position (n=75). The FDG-PET/CTA imaging is performed in the early and late and chronic postoperative episode (group 1, 2 and 3 respectively):

• Early postoperative (group 1, n=25): 5 (± 1) weeks after PHV implantation .

• Late postoperative (group 2, n=25): 12 (± 2) weeks after PHV implantation .

• Chronic postoperative (group 3, n=25): 12 (± 2) months after PHV implantation.

We will only include patients in group 3 in case FDG uptake around the PHV in group 2 results in moderate or severe FDG uptake according to the QVSH score in 1 or more patients.
Of note: patients cannot be included in two groups.

Main study parameters: 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.

Study objective

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 design

cross-sectional

Intervention

PET-CT and CTA

Contacts

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Eligibility criteria

Inclusion criteria

Age ≥ 50 years

Patients after uncomplicated PHV implantation in aortic position (mechanical and biological PHVs).

Normal routine follow up TTE (standardly performed 5 days after operation). With no signs of obstruction, endocarditis or significant paravalvular leakages.

Group 1: 5 (± 1) weeks after PHV implantation (n=25).

Group 2: 12 (± 2) weeks after PHV implantation (n=25).

Group 3 : 12 (± 2) months after PHV implantation (n=25). Inclusion in group 3: only in case of ≥ 1 patients with post-operative moderate/severe uptake (QVSH score) in group 2.

Weight < 110 kg

Exclusion criteria

Known contrast allergy

Known renal impairment (GFR<60)

Diabetes Mellitus

Mild contractile dysfunction of the left and/or right ventrical (Eyeballing, Ejection fraction <45 %, TAPSE <14 mm)

Active cardiac decompensation

Uncontrolled cardiac arrhythmias

Suspicion on active endocarditis

Previous participation in scientific studies using radiation.

(Possible) pregnancy in pre-menopausal women above 50 years not on reliable birth control therapy. Other contraindications for contrast use according the standard daily clinical routine according to the protocol “Protocol preventie contrastreactie en contrastnefropathie” by the department of radiology UMCU or EMC

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

Refusal to be informed about potential additional CTA or FDG-PET findings

If already included in group 1 (early post operative phase), patients cannot be included in group 2 or 3 (late post operative phase).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-05-2013
Enrollment:	75
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-06-2016
Application type:	First submission

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	NL5478
NTR-old	NTR5895
Other	NL42743.041.12 : 12-633

Study results