Is CABG-induced vascular inflammation detectable by FDG-PET/CT? A pilot study

Published: 01-07-2014
Last updated: 21-04-2024

To explore FDG-PET/CT to quantify the effect of CABG on inflammation in the arterial wall.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational invasive

Summary

ID

NL-OMON40789

Source
ToetsingOnline

Brief title
CABG and PET/CT

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Atherosclerosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: CABG, FDG-PET/CT, Vascular inflammation

Outcome measures

Primary outcome

Percentage change in FDG uptake after CABG as compared with baseline in the

arterial wall of aortic arch, carotid arteries and descending aorta.

Secondary outcome

Not applicable

Study description

Background summary

Patients who undergo Coronary Artery Bypass Grafting (CABG) supported by extracorporal circulation have 2-3 times more risk to experience an ischemic Cerebro Vascular Accident (CVA) during the first year after surgery as compared to similar patients who undergo a percutaeneous coronary angioplasty (PCA) for revascularisation. We hypothesize that this increased risk is caused by an arterial inflammatory response in aorta and carotid arteries triggered by this major surgery and that this response can be visualized by FDG-PET/CT (Fluor-deoxyglucose-positron emission tomography combined with computer tomography). If true, this would provide us with an important tool to perform phase 2 studies to select appropriate therapy to reduce the risk for CVA after CABG.

Study objective

To explore FDG-PET/CT to quantify the effect of CABG on inflammation in the arterial wall.

Study design

Observational pilot study that explores the effect of CABG on deoxyglucose-uptake in the arterial wall of aortic arch, carotid arteries and descending aorta as detected by FDG-PET/CT. A diagnostic procedure (FDG-PET/CT) before CABG (at most 1 months interval) and during the first week after CABG will be performed.

Study burden and risks

On top of the already scheduled CABG procedure, patients will undergo a FDG-PET/CT twice. This diagnostic procedure will be performed according to standard state-of-the-art clinical procedures at the department of Nuclear Medicine. Duration of each procedure: 2 hours. Procedure-related exposure to radioactivity: 13 mSv for two procedures (with a low-dose CT from skull base to thigh). The main risk is the detection of still undiagnosed malignancy by FDG-PET/CT. In such an event, the CABG surgery will not be cancelled or delayed, but the patient will be offered an off-pump procedure. Any necessary additional diagnostic procedures to optimally diagnose and treat the malignancy will be performed after surgery, unless it is decided otherwise in the best benefit of the patient).

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 21
Nijmegen 6525 EZ
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 21
Nijmegen 6525 EZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Age: at least 18 years
* Scheduled for CABG with extracorporal circulation
* Informed consent

Exclusion criteria

* MDRD-eGFR < 40 ml/min/1.73 m2
* History of polymyalgia rheumatica and/or giant cell arteritis
* Chronic use of anti-inflammatory drugs (such as NSAID's (acetylsalicylic acid <100 mg excluded) or prednison)
* History of a mycotic aneurysm.
* Any physical (for example movement disorders or severe orthopneu) or psychiatric condition (for example claustrophobia) that interferes with the ability for the patient to undergo a FDG-PET/CT scan.
* Active infection that interferes with imaging of aorta by FDG-PET/CT.
* Diabetes Mellitus

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	6
Type:	Anticipated

Ethics review

Approved WMO

Date:	01-07-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL49409.091.14