PET-CT and its RElationship in detection of Coronary plaques with Intravascular imaging methods: Optical coherence tomography (OCT) and intravascular UltraSound (IVUS)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON36003

Source
ToetsingOnline

Brief title
PRECIOUS

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
instable plaque, vulnerable plaque

Research involving
Human

Sponsors and support

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

Intervention

Keyword: IVUS, OCT, PET-CT, vulnerable plaque

Outcome measures

Primary outcome

1. Correlation between Target-to-Background Ratios (TBRs) and necrotic core in contact with lumen (NCCL) / Plaque Burden (PB) measured with IVUS.

2. Correlation between TBRs and fibrous, fibrolipidic, necrotic core, or calcium content of plaques found with IVUS in every ROI.

3. Correlation between TBRs and macrophage quantification / cap thickness on OCT in every ROI.

4. Correlation in median and max TBR between coronary arteries and the other investigated arteries.

Secondary outcome

1. Correlation between biomarkers and macrophage quantification/ cap thickness on OCT.

2. Correlation between biomarkers and max TBR on PET-CT.

3. Correlation between NCCL, PB, plaque content found with IVUS-VH and cap thickness found on OCT.

Study description

Background summary

Acute coronary syndrome (ACS) is often the first clinical presentation of atherosclerosis. Angiographic and clinical findings are poor predictors of ACS. This has led to the development of the concept of vulnerable plaque: a plaque which is prone to rupture or highly thrombogenic, and therefore carries a high risk of causing ACS. As a consequence, a considerable patient population with subclinical coronary artery disease (CAD) is at risk of developing ACS in the near future. The ultimate goal in the field of ACS is the detection of vulnerable plaques even before ACS develops, which may create the possibility to prevent ACS with medical or interventional treatment. To achieve this, it is of immensely importance to develop a method to detect vulnerable plaques non-invasively. One important characteristic of a vulnerable plaque is active inflammation as a result of extensive macrophage accumulation. PET-CT has shown to be an excellent imaging modality to detect even small amounts of inflammation. In this study, we will investigate whether PET-CT findings correlate with characteristics of vulnerable plaques found with the invasive methods intravascular ultrasound (IVUS) and optical coherence tomography (OCT).

Study objective

The proposed project will have the following objectives:
1. To investigate the correlation between 18F-FDG accumulation in plaques seen on PET-CT and plaque characteristics found with IVUS-VH and OCT.
2. To investigate the correlation between inflammation of the coronary arteries and inflammation in other arteries (carotid, aortic and femoral arteries).
3. To evaluate the correlation between 18F-FDG accumulation in plaques and serum biomarkers in all groups.

Study design

Patients are eligible for this study if they have a clinical indication for percutaneous coronary intervention after they have been diagnosed with non-ST-segment elevation myocardial infarction (NSTEMI) within the previous 5 days. Before any study-related procedure, written informed consent is obtained. After coronary angiography, IVUS-VH and OCT measurements of the culprit lesion is performed prior to PCI, except when ischemia is seen when IVUS-VH- or OCT-catheters are passing the culprit lesion. If the PCI is successfully performed, i.e. the remaining stenosis is less than 20 percent and no dissection is made, patients undergo IVUS-VH and OCT, if suitable (at discretion of the operator), in all three coronary arteries (including the target vessel). As soon as possible, but at least within 72 hours after PCI, patients will undergo 18F-FDG PET-CT. The findings of 18F-FDG PET-CT and IVUS-VH/OCT will be analyzed and compared.

Study burden and risks

Patients are exposed to extra radiation burden due to injection of radio-active glucose (18)F-FDG prior to PET scan, radiation due to low dose CT during PET-CT, and the catheterization is elongated with 20minutes (although only a couple of minutes extra fluorescence time). Because during the IVUS and OCT assessment, extra catheters are placed in the coronary tree, there is a slightly increas in the risk for dissection, or procedure related myocardial infarction.

The burden associated with participation in this study consists of 2 times 20 minutes anamnesis, physical exam and EKG and elongation of the catheterization with 20 minutes. The duration of the PET-CT (including preparation) will be approximately 6 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

Consecutive patients with symptoms of acute coronary syndromes without ST-segment elevation are eligible for this study if the following three inclusion criteria apply:
a. One or more episodes of anginal symptoms at rest or at minimal exertion within the last 5 days, presumed to be ischemic in origin and lasting at least 5 minutes
b. Troponin or CKMB concentration above the upper reference limit
c. An indication for percutaneous coronary intervention (PCI) of a de novo culprit lesion with at least one non-culprit vessel with a 40mm proximal segment without stenoses of more 50%, suitable for IVUS and OCT

Exclusion criteria

a. Persistent ST-segment elevation of >1mm in two or more contiguous electrocardiographic leads
b. Impaired renal function (eGFR <60 mls/min/1,73 m2).
c. Hypotension (Systolic BP <90 mmHg), decompensated heart failure, shock, refractory ventricular arrhythmias, acute conduction system disease, implanted defibrillator, or left ventricular ejection fraction *30%.
d. Known allergies to aspirin, all thienopyridines (Plavix ®, Effient ®), heparin, stainless steel, copper or a sensitivity to contrast media which cannot be adequately pre-medicated.
e. Disabling stroke within the past year.
f. History of significant gastro-intestinal bleeding, bleeding diathesis or coagulopathy.
g. Any prior bypass graft surgery.
h. Prior or planned heart transplant or any other organ transplant.
i. Planned major non-cardiac (for example oncological) surgery.
j. Life expectancy of less than one year or factors making clinical follow-up difficult
k. Previous participation in this study or participation in another study with any investigational drug or device within the past 30 days (study participation ends after completion of the final follow-up).
l. Women who are pregnant or women of childbearing potential who do not use adequate contraception.
m. Patients known with diabetes mellitus.
n. Inability to comply with the specific follow -up evaluation
o. Restenosis of a (previously treated) culprit lesion
p. Untreated left main disease with > 50% stenosis.
q. Significant, diffuse 3-vessel coronary artery disease, requiring treatment.
r. Known tendency to coronary vasospasm.
s. Not possible to perform 18F-FDG PET-CT within 72 hours after PCI.
t. Persistent irregular heart rhythm

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2012
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL35482.018.11