Prospective comparison of cardiac PET/CT, SPECT/CT perfusion imaging and CT coronary angiography with invasive coronary angiography

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

Summary

ID

NL-OMON39411

Source
ToetsingOnline

Brief title
The PACIFIC-trail

Condition

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

Synonym
'coronary artery disease' atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Nederlandse Hartstichting

Intervention

Keyword: Cardiac imaging, Invasive coronary angiography, PET/CT, SPECT/CT

Outcome measures

Primary outcome

quantitative myocardial blood flow values obtained with PET/CT imaging.

Quantitative myocardial perfusion images obtained with SPECT/CT.

Quantification of the myocardial infarct size using MRI.

Coronary artery stenosis severity obtained with invasive coronary angiography

Fractional Flow Reserve values obtained during invasive coronary angiography

Intracoronary Doppler Flow measurements

Assessment of myocardial perfusion using thermodilution

Sensitivity, specificity, positive and negative predictive value will be calculated. In additional, a combined analyses of both PET/CT and CTCA as well as SPECT/CT and CTCA results will be performed to evaluate the surplus value of combined imaging.

Secondary outcome

n.a.

Study description

Background summary

Coronary artery disease (CAD) is the leading cause of death in the western industrialized world. An early and accurate diagnosis of CAD allows to initiate adequate treatment in order to reduce morbidity and mortality. The gold standard for the diagnosis of CAD is invasive coronary angiography (ICA), to visualize a luminal stenosis of one of the major coronary artery branches, in conjunction with fractional flow reserve (FFR) measurements, to evaluate the potential hemodynamic significance of such a stenosis. Unfortunately, the invasive nature if ICA and its associated complications such as bleeding, cerebral vascular accidents due to embolization, cardiac arrhythmias, and even death warrants the use of non-invasive techniques to accurate act as a gate-keeper for catheterization-lab referral in order to reduce the number of purely diagnostic ICAs. Single photon emission tomography (SPECT) with 99Tc-technetium labeled flow tracers is most frequently used to non-invasively visualize regional flow impairment to detect flow limiting stenoses. Although sensitivity of SPECT is fairly accurate (~85-90%), specificity is somewhat hampered (~75-80%) due to attenuation artifacts.(3) Positron emission tomography (PET), with routine correction of attenuation, significantly reduces the number false positive scans by reducing attenuation artifacts. Moreover, the greater spatial resolution of PET and its ability to express perfusion quantitatively, significantly enhances sensitivity. PET, however, is currently only used on a limited scale due to its high costs and technical demands concerning the manufacturing and administration of PET perfusion tracers. In recent years, however, both SPECT and PET systems have been fused with computed tomography (CT). As the density map obtained with the CT equipment allows to correct for tracer attenuation, SPECT/CT is expected to enhance its specificity by reducing attenuation artifacts and may even approach the diagnostic accuracy of PET. Data to substantiate this hypothesis are, however, lacking. Furthermore, previous studies have demonstrated that infarctions may have an impact not only on the perfusion in the infarct related territory, but also on perfusion in non-infarct related vascular territories. The current study will, therefore, determine the impact of chronic myocardial infarctions on PET and SPECT perfusion imaging. The current myocardial perfusion imaging criteria for ischemia are probably not appropriate for patients with a previous myocardial infarction. Subsequently the diagnostic accuracy of myocardial perfusion imaging in these specific patient population will be determined using invasive coronary angiography and fractional flow reserve measurements as the reference standard.

Study objective

The aim of this study is to perform a head-to-head comparison between SPECT/CT and PET/CT in comparison with conventional catheter-based coronary angiography and FFR measurements, to establish the diagnostic value of the modern cardiac myocardial perfusion scanners in patients with a previous myocardial

infarction.

Study design

Prospective single center trial

Study burden and risks

Benefits and risks assessment

Risk assessment:

Participants will be exposed to a total of 1.8 mSv for the entire PET protocol (0.8 mSv for the entire PET session and 1.0 mSv for the attenuation correction scans). SPECT/CT generates a radiation dose of 5 mSv, and conventional invasive coronary angiography carries a radiation dose of 5 mSv.
In conclusion, participants will be exposed to a total radiation dose of approximately 12 mSv, equaling maximal annually radiation dose of 20 mSv for healthcare employees. By comparison, a single CT abdomen produces a radiation dose of approximately 15 mSv.

To minimize the risk of contrast-induced nephropathy, glomerular filtration rate must exceed 45 ml/min. Furthermore, metformin needs to be discontinued on the day of the MRI scan and 48 hours after MRI in subjects with a glomerular filtration rate beneath 60 ml/min in order to prevent metformin induced lactic acidosis and contrast induced nephropathy.

Appropriate medication is present to abolish side-effects of contrast-agents and adenosine.

Benefits:

- Patients receive additional information regarding the functional and anatomical status of their hearts.
- Invasive coronary imaging and potential percutaneous coronary interventions are facilitated by additional information obtained with myocardial perfusion imaging.
- Lungs and part of the digestive tract will be evaluated for coincident pathological findings with the use of MRI.

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

- Presenting with chest pain to the cardiologist.
- Previous myocardial infarction
- Presenting for a clinically referred invasive coronary angiography
- Age above 40 years

Exclusion criteria

- History of severe COPD or chronic asthma
- Pregnancy
- Renal failure (i.e. eGFR < 45ml/min)
- Use of sildenafil (Viagra) or dipyramidol (Persantin)
- Allergic reaction to iodized contrast
- Concurrent or prior (within last 30 days) participation in other research studies using investigational drugs
- Claustrophobia

- Significant co-morbidities
- Atrial fibrillation, second or third degree atrioventricular block
- Tachycardia
- Acute myocardial infarction
- Previous radiation exposure in the diagnostic work-up
- Individuals with metal implants that are not MRI proof
- Subjects intended for short-term medical treatment or an invasive coronary intervention
- No informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-01-2012
Enrollment:	210
Type:	Actual

Ethics review

Approved WMO Date:	03-01-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-11-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	26-06-2013
Application type:	Amendment
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	NL33941.029.10