High and intermediate risk SPECT-CT optimization study

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

Summary

ID

NL-OMON33985

Source
ToetsingOnline

Brief title
"HOROSCOPE Study"

Condition

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

Synonym
coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Coronary Angiography, Coronary artery disease, Multislice CT, SPECT

Outcome measures

Primary outcome

We propose a study to evaluate the clinical significance of MSCT-CA and SPECT fusion imaging. To decide whether the new diagnostic strategy should actually replace the current strategy a study that evaluates the effect on decision making is needed. Since it is unethical to perform a randomized controlled trial to evaluate the new diagnostic process we compare the hypothetical therapeutic decisions by a panel of cardiologists, a cardio-thoracic surgeon, a radiologist and a nuclear medicine physician.

The primary endpoint of this study will be the therapeutic modalities indicated by the routine *heart team* and the panel evaluations. The panel will decide in each patient among three strategies:

i. No action taken other than therapeutic advice and/or additional medication,

or

ii. Revascularization by percutaneous coronary intervention (PCI), or

iii. Revascularization by coronary artery bypass grafting (CABG).

Two secondary endpoints have been defined for this study. 1. The performance of the MSCT-CA and SPECT scan images in diagnosing hemodynamically significant coronary artery disease will be determined versus the gold standard, invasive coronary angiography. 2. The additive value of fusion images of the MSCT-CA and SPECT by direct overlay technique will be evaluated for their incremental value in diagnosing hemodynamically significant coronary artery disease versus

separate MSCT-CA and SPECT images.

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Study description

Background summary

Both physician and patient will benefit from an imaging technique that provides both anatomical and functional information of coronary artery disease, preferably in a one stop, one shop, and non-invasive modality. Currently invasive coronary angiography is the reference standard for evaluating the anatomic severity and Single-Photon Emission Computed Tomography (SPECT) is the current reference test for the assessment of the functional severity of coronary artery disease. Multislice computed tomography coronary angiography (MSCT-CA) has been proposed as non invasive imaging modality for anatomical evaluation of patients with suspected CAD. With the 64-slice MSCT high positive and negative predictive values for significant coronary artery stenosis have been reported not only in native coronary arteries but also in coronary artery bypass grafts. Fusion of MSCT-CA and SPECT images could lead to the non-invasive imaging modality by which the anatomic and functional extend of CAD is fully evaluated, without the risk of complications induced by the invasive nature of routine coronary angiography.
Allthough a recent multicenter and multivendor 64-slice MSCT-CA study states that its value lies mainly in ruling out significant CAD; it lacks a sufficient positive predictive value to relieably demonstrate obstrictive coronary artery disease.
Fusion of MSCT-CA and SPECT images could lead to the non-invasive imaging modality by which the anatomic and functional extend of CAD is fully evaluated, without the risk of complications induced by the invasive nature of routine

coronary angiography.

Study objective

The primary objective is to compare whether results from fusion imaging of MSCT-CA and myocardial perfusion SPECT lead to similar or different therapeutic choices as compared to results from myocardial perfusion SPECT and invasive coronary angiography in patients with known CAD and recurrent angina or with an intermediate to high pretest likelihood of CAD.

Secondary objectives are:
1. Comparing the performance of the MSCT-CA and SPECT scan images in diagnosing hemodynamically significant coronary artery disease versus invasive coronary angiography and SPECT.
2. The additive value of fusion images of the MSCT-CA and SPECT by direct overlay technique will be evaluated for their incremental value in diagnosing hemodynamically significant coronary artery disease versus separate MSCT-CA and SPECT images.

Study design

The study is designed as a single centre cross-sectional cohort study. A series of 400 patients, with known CAD and recurrent angina or an intermediate to high pre-test likelihood of CAD, will be included. Patients with a history of percutaneous coronary intervention (PCI) or coronary bypass grafting (CABG) will be included in the trial. All patients will be recruited in our outpatient clinic. After informed consent has been obtained, all patients included in the study will undergo a systematic diagnostic work-up which includes MSCT-SPECT imaging and coronary angiography. On the first day SPECT images will be obtained after physiological or pharmacological stress directly followed by an MSCT-CA scan. An abnormal perfusion pattern, showing a defect in at least a single segment, after stress will lead to a rest SPECT scan on the second day of imaging. A normal perfusion pattern after stress SPECT imaging will exclude the subject from further SPECT imaging. On the second day of imaging a rest SPECT scan will be performed if perfusion defects were visualized by the stress SPECT images. This will be followed by a standard coronary angiogram using fractional flow reserve (FFR) to determine the functional severity of an intermediate coronary stenosis. All imaging procedures will be performed within a period of two weeks. Afterwards the treatment plan is routinely discussed in the so-called *heart-team* meeting between a thoracic surgeon and a cardiologist, and actual medical or revascularization therapy is carried out. After one year follow up data will be collected on medication use, ischemic cardiac events, presence of heart failure symptoms, cardiac arrhythmias, revascularization procedures, hospitalization, device therapy (f.i. pacemakers) and survival.
The relevance of the diagnostic process using MSCT-SPECT imaging as the sole

modality will be evaluated through comparing the therapeutic modalities chosen by a panel of cardiologists, a thoracic surgeon, a radiologist and a nuclear medicine physician. In three sessions the panel will evaluate three different data sets, one including SPECT and CAG data, one including MSCT-SPECT data and one including all imaging data. Additional panel sessions will be scheduled, with the addition of 1-year follow up data to the decision-making process, when the first panel sessions lead to a significant difference in the given therapeutic advice.

Study burden and risks

By performing an extra Multislice CT Angiography the sudy subjects will be exposed to an extra radiation dose of approximately 10 MSv.
Also, in this protocol the sudy subjects will be exposed to iodide containing contrast agents. The use of these agents bares a small risk of a hypersensibility reaction or contrast induced renal insufficiency.
These risk are additive to the risks that the subjects are exposed to during the routine diagnostic evaluation; the invasive coronary angiogram and the SPECT scan.

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

a. The subject is a man and is 45 years of age or older in case of no known history of CAD and 18 years of age or older if the subject has a history of CAD. Or the subject is a woman and 45 years of age or older, in case of a known history of CAD and if the subject has no history of CAD.
b. Written informed consent is obtained.
c. The subject has the clinical suspicion of having (recurrent) angina pectoris or an equivalent, based on history taking, clinical examination and baseline diagnostic testing (e.g. ECG recording and laboratory tests).
d. The subject has an intermediate or high risk of suffering from symptomatic coronary artery disease based on the combined Diamond and Forrester and CASS data. Using cutoff values of <13%, >87% and in between for low, high and intermediate risk of coronary artery disease respectively.
e. The patient has a history of percutaneous coronary intervention or coronary artery bypass grafting.

Exclusion criteria

a. The subject is suffering from unstable angina pectoris.
b. The subject is suffering from decompensated congestive cardiac failure.
c. The subject is suffering from a known non-ischemic cardiomyopathy
d. The subject is suffering from a cardiac rhythm other than sinus rhythm.
e. The subject is or might be pregnant.
f. The subject is morbidly obese (BMI > 40).
g. The subject is not able to sustain a breath-hold for 25 seconds.
h. The subject is unable to remain in supine position for at least 30 minutes.
i. The subject has known allergies to or contra-indications to receiving an iodinated contrast agent.
j. Clinical condition prohibiting subsequent interventional therapy as indicated by the results of the imaging procedures.
k. There is a severe language barrier.

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):	23-10-2009
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO

Date:	01-05-2009
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL25791.100.09
Other	Volgt.