

Assessment of acute chest pain by computed tomography angiography

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

Summary

ID

NL-OMON33025

Source

ToetsingOnline

Brief title

Acute chest pain by CT angiography

Condition

- Coronary artery disorders

Synonym

Acute coronary syndrome

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: acute coronary syndrome, computed tomography, diagnosis, triage

Outcome measures

Primary outcome

- 1) Accuracy to detect/exclude ACS based on: coronary obstruction, plaque, myocardial enhancement, alternative diagnoses.
- 2) Evaluate the (potential) consequences of a CT-based approach in terms of: admissions, catheterizations, time, expenses.
- 3) Ability of CT to detect vulnerable plaque (on OCT), based on: plaque density, size, calcification, eccentricity, remodeling.

Secondary outcome

- 1) Identify patient subcategories in whom CT angiography had most (or least) relevant diagnostic value, based on: demographics, clinical presentation, initial test results: ECG, biomarkers, CT-specific characteristics: heart rate, BMI.
- 2) Correlation between CT angiography and catheter angiography for the detection of coronary stenosis.
- 3) Correlation between CT angiography and exercise testing for the detection of significant coronary artery disease.
- 4) Respective diagnostic contributions of CT angiography, plaque imaging and myocardial enhancement.

Study description

Background summary

The current work-up of patients with acute chest pain and a possible acute coronary syndrome (ACS) is difficult, inefficient and errors are common. On a daily basis physicians are forced to make a decision whether or not to admit a patient with chest complaints, based on clinical insight, a rough estimation of risk, but without evidence that an ACS is absent. Because of the potentially catastrophic consequences of premature discharge physicians tend to be conservative and practice a low threshold for admitting patients for observation and noninvasive testing. The majority of patients admitted do not have an ACS, while a small but significant number (3-5%) of patient sent home end up having a myocardial infarction.

Noninvasive imaging has developed into an accepted technique in stable chest pain patients, and may also be useful in patients with acute chest complaints as it images several relevant cardiac aspects: coronary obstruction, atherosclerotic plaque, myocardial hypoperfusion and non-cardiac thoracic emergencies.

Study objective

We hypothesize that early CT imaging allows better and faster triage (without the need for prolonged observation) of patients with acute chest pain: early discharge of the majority without significant coronary or other life-threatening conditions and earlier coronary intervention of those with significant disease before repeated blood tests or stress tests indicate to do so.

A number of investigators have studied the potential value of CT in patients with acute chest pain. Despite promising, preliminary results, particularly to exclude ACS, in these low-risk patients, without ECG changes or elevated cardiac markers, results were negatively affected by non-interpretable scans and low rates of ACS. However many unresolved issues remain: which patients benefit most (or not at all), how will CT perform in a Dutch/European setting, can we reduce the rate of nondiagnostic tests with current state-of-the-art technology, how will CT perform in intermediate-high risk patients, can CT avoid catheterization in patients with minimally elevated biomarkers, how does myocardial enhancement imaging add, in how many patients can CT replace noninvasive testing.

Invasive coronary lumenography identifies coronary stenosis but is unable to investigate the vessel wall. Intra-coronary imaging can be helpful to investigate the coronary vessel wall, to detect plaque, plaque disruption or thrombus. Optical coherence tomography (OCT) is a light-based intravascular imaging technique with a very high spatial resolution and can provide direct visual evidence of plaque disruption as the cause of an acute coronary syndrome. OCT images can be used to investigate the ability of MSCT to identify vulnerable or culprit plaques.

The ultimate goal is to develop a system that allows better triage of patients with acute chest pain to earlier identify of patients who need intervention and salvage more heart muscle, and at the same time reduce unnecessary hospital admission and testing in patients without a symptomatic coronary artery disease. Based on these results, we will be able to design a randomized trial, in a (sub)population that is expected to benefit most from early, noninvasive coronary imaging, using parameters that best differentiate patients with or without an ACS, to investigate the diagnostic and economic consequences of a CT-guided or standard approach to patients with suspected acute coronary syndrome.

Study design

This is a prospective, observational study. After the necessary, standard procedures have been completed, consenting study participants will undergo a non-invasive coronary angiography by contrast-enhanced, ECG-synchronized computed tomography, to assess: a) coronary atherosclerosis; b) coronary obstruction; c) myocardial hypoenhancement; d) alternative causes of acute chest pain. After a preparational scan to determine the position of the heart within the chest, a low-dose, non-enhanced scan will be performed to assess the coronary calcium burden. In case of a high heart rate ($>80/\text{min}$), and in the absence of contraindications, a betablocker will be administered. After iv contrast injection (80ml) the CT coronary angiogram is acquired. If important (non-coronary) pathology is detected the blinding will be broken and the attending physician will be notified. After the CT scan the patient will continue the clinical workup for possible ACS. Depending on the results patients will either undergo cardiac catheterization or be observed with additional blood tests and a noninvasive stress test. A single bloodsample will be taken and stored, which may be used for measurement of biomarkers. If patients at high risk (based on presentation and test results) need to undergo catheterization, then OCT will be performed as well during this procedure, which will provide evidence for plaque rupture as the cause of the acute coronary syndrome.

At 6 months patients will receive a questionnaire by mail, to assess whether cardiovascular events occurred after initial evaluation.

Study burden and risks

The CT examination is relatively short, well tolerated by most, without significant extension of the patients stay at the ER. Iodine containing contrast medium potentially affects the kidney function, although significant dysfunction is rare in patients with a normal baseline kidney function. Allergic reactions can occur but severe symptoms are rare. Roentgen exposure (2-5 mSv, annual background radiation 3.6 mSv) will be minimized, but a very small risk of significant disease remains. Betablockers used in a small number of patients without contraindications is generally regarded as safe, but may

cause hypotension or bradycardia (which is the reason for giving it).

Optical coherence tomography, performed in ± 50 patients, will prolong the catheterization by 10-15 minutes, and may result in vessel wall damage in very rare cases. Current OCT technology is well tolerated.

After 6 months patients will be requested to fill out and return a questionnaire.

The investigated patient group will also be one benefiting from the study results in the future. In case of CT evidence other relevant (non-coronary) findings the blinding will be broken, and the patient may benefit from earlier diagnosis and treatment.

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

Patients, >40 years, with acute chest pain, suspected for an acute coronary syndrom

Exclusion criteria

When immediate coronary angiography is indicated (ST-elevatie myocardial infarction, hemodynamic instability, significant arrhythmia).

When an acute coronary syndrome is very unlikely based on presentation, demographics, risk factors and initial test results.

CT contrast medium allergy, impaired renal function, pregnancy.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 01-07-2009

Enrollment: 150

Type: Actual

Ethics review

Approved WMO

Date: 25-06-2009

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL27048.078.09