Better Evaluation of Acute Chest Pain With Computed Tomography * a Randomized Prospective Trial

Published: 10-05-2011
Last updated: 27-04-2024

To compare the diagnostic value of CTA versus the standard work-up in terms of identifying patients with severe coronary artery disease (requiring revascularization), as well as the ability to safely discharge patients without coronary artery…

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

Summary

ID

NL-OMON39354

Source
ToetsingOnline

Brief title
BEACON trial

Condition

- Coronary artery disorders

Synonym
Coronary artery disease

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 chest pain, Computed tomography, Coronary artery disease, Exercise electrocardiography

Outcome measures

Primary outcome

1) The proportion of patients discharged from the ED without adverse events in the following 30 days. Adverse events are defined as death, non-fatal myocardial infarction or coronary revascularisation.

2) The diagnostic yield is defined as the number of patients with severe coronary artery disease (by invasive angiography). Severe coronary artery disease is defined as a flow limiting or highly vulnerable plaque in one or more vessels, requiring revascularization according to established guidelines.

Secondary outcome

a) Successful discharge rate for all adverse events (at 30 days): death, non-fatal MI, unstable angina, coronary revascularization, and repeat hospital visits for chest pain.

b) Composite endpoint of major adverse cardiac events at 6 months: cardiac death, non-fatal myocardial infarction, unstable angina and repeats hospital visits for chest pain.

c) Diagnosis of acute coronary syndrome (cardiovascular death, myocardial infarction, instable angina according to the European guidelines of cardiology16) at time of discharge.

d) Late myocardial ischemia (at 2-day follow-up).

e) Duration of hospital stay.

f) Direct medical costs until 30th day after ED visit.

g) Radiation exposure

Study description

Background summary

The current work up of suspected acute coronary syndrome, based on presentation, symptoms, ECG and biomarkers, is not efficient and results in unnecessary diagnostics and hospital admissions, as well as errors or delayed diagnoses, in a substantial number of patients. Computed tomography angiography (CTA) images atherosclerosis, coronary obstruction as well as myocardial hypoperfusion. We hypothesize that early use of CTA is of incremental value and allows for accurate and immediate triage of patients with acute chest pain.

Study objective

To compare the diagnostic value of CTA versus the standard work-up in terms of identifying patients with severe coronary artery disease (requiring revascularization), as well as the ability to safely discharge patients without coronary artery disease or other potentially life-threatening conditions.

Study design

This study is designed as a single as well as a multicenter randomized controlled trial with distinctive study endpoints. In the single center (Erasmus MC) part we will assess whether CTA will allow safe ED discharged without any major cardiac adverse events in the next 30 days.
In collaboration with other hospitals we will be able to recruit a sufficient number of patients to assess whether the CT approach will identify more patients with severe coronary artery disease (by invasive angiography, requiring revascularization).

Participating patients presenting with acute chest pain, suspected of having an ACS, are randomly allocated to either the control group with the standard work-up, based on European guidelines or to the intervention group with diagnostic workup with CTA.
The diagnostic accuracy and efficiency of coronary CTA on patient management will be evaluated. Patients will be recruited from the emergency ward over a period of approximately 18 months. Blood analysis and ECG will be repeated two days after visiting the ER in patients who were immediately discharged without

observation. Further follow-up will take place after 30 days (out patient clinic) and 6 months (telephone interview, or mailed questionnaire), mortality records and hospital records.

Intervention

Diagnostic intervention with replacement of the standard optimal care (based upon serial blood testing and stresst testing) by a strategy based upon cardiac CT-scan.

Study burden and risks

1) Patients will receive iodine contrast medium. Known allergies or kidney dysfunction are contraindications to iodine contrast. The risk of kidney dysfunction is small in patients with a normal kidney function (which will be checked). Allergic reactions are rare. Medication and personnel is available to deal with unexpected reactions. Patients with minimal or uncertain reactions in the past will be pre-medicated with H2-antagonists and corticosteroids. Contrast extravasation can cause skin damage but it is rare and can be limited by special extravasation detectors.
2) The total radiation dose is <5 mSv for CT angiography, which is more than the annual background exposure, but less than catheter angiography or nuclear imaging. The associated risks are considered to be very small.
The CT examination is generally well tolerated, probably better than the cardiac catheterization or hospital admission which will be more frequent in the standard care group.

Time burden:
There are no significant physical burdens. In terms of time, participation will take a few hours over 6 months, consisting of two hospital visits and one questionnaire.

Benefits & group relatedness:
If the hypothesis is correct, then patients that underwent CT will benefit. In general, participation to the study benefits similar patients in the future.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL

Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's-Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Acute chest pain or equivalent possibly caused by coronary artery disease. Age >30 years, ability and willingness to provide informed consent.

Exclusion criteria

History of significant CAD, defined as prior myocardial infarction, percutaneous coronary intervention (PCI) or coronary artery bypass graft (CABG) surgery.
Very low likelihood of an ACS, based on demographics, risk factors and presentation (normal ECG and initial markers), without clinical requirement for observation or further investigation.
Very high-risk ACS with need for immediate coronary angiography (<90 minutes), according to clinical guidelines.
Troponins > 0.1, high risk patients who will require early invasive angiography (<48 hrs).
Clinical instability: clinical heart failure and hemodynamic instability
Contra-indications to CT: kidney failure, allergic reactions to contrast media, pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-06-2011
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	10-05-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	16-09-2013
Application type:	Amendment
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	NL35422.078.11