Modification of risk with MSCT- coronary angiography in high-risk cardiac asymptomatic patients.

Published: 08-01-2008
Last updated: 11-05-2024

To demonstrate whether using MSCT to reclassify individuals who are at high-risk based on traditional risk factors.

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

Summary

ID

NL-OMON39448

Source
ToetsingOnline

Brief title
MSCT coronary imaging in asymptomatic high-risk patients

Condition

- Coronary artery disorders

Synonym
Atherosclerosis, coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Nederlandse hartstiching

Intervention

Keyword: Cardiovascular diseases, Familial Hypercholesterolaemia, High-risk patients, MSCT Imaging

Outcome measures

Primary outcome

Primary endpoint:

Difference in risk prediction from MSCT-derived information compared to

traditional risk factors

Primary Outcomes:

1. proportion of patients at high-risk reclassified with CT-calcium score into

low, medium and high-risk

2. proportion of patients at high-risk reclassified with CT-coronary imaging

(total plaque burden) into low,

medium and high-risk

Secondary outcome

Secondary endpoint:

A) combination of cumulative death, non-fatal myocardial infarction or stroke

during 5-year follow-up

B) combination of death, non-fatal myocardial infarction or angina pectoris

(positive stress-test) in patients

with FH

C) all-cause death during 5-year follow-up

Secondary outcomes:

1. risk classification according to calcium score based on coronary tree,

vessel or segment score

2. risk classification according to CT-coronary imaging and total plaque burden

per coronary tree, vessel

and segment.

Study description

Background summary

Acute cardiac death or nonfatal myocardial infarction is the first clinical manifestation of coronary atherosclerosis which occurs in 40% to 50% of cases[1,2]. Eighty % of CHD mortality in individuals <65 years occurs during the first heart attack and 57% of men and 64% of women who died suddenly of CHD had no previous symptoms [3,4] Traditional risk factors are used to define the statistical likelihood of development of an adverse coronary event, but they provide no direct evidence of the presence or degree of coronary atherosclerosis. Traditional risk factors fail to detect an individual who will suffer a cardiovascular adverse event, necessitating better methods of risk stratification [5]. Early detection of atherosclerosis itself before symptoms occur can provide a major opportunity to prevent the occurrence of adverse cardiac events. The predictive value of traditional risk factors may be increased by direct non-invasive MSCT-derived demonstration of subclinical coronary atherosclerosis. MSCT coronary
imaging identifies individuals without or with varying degrees of subclinical atherosclerosis and this may result in a more precise reclassification of high-risk individuals based on traditional risk factors into low, medium, high or very
high-risk groups.This reclassification allows tailoring of the intensity of risk management proportional to the re-allocated risk group, which may reduce costs.

Study objective

To demonstrate whether using MSCT to reclassify individuals who are at

high-risk based on traditional risk factors.

Study design

Prospective multicentre blinded observational study of high-risk patients undergoing CT-coronary imaging with long-term (5 Years) follow-up.

Study burden and risks

The likelihood of additional mortality associated with radiation exposure causing carcinoma is:

mSv Likelihood mortality
Coronary calcium scan 1.3 - 2.0 1 per 10.000
CT-coronary angiography 4.8 - 14 1 per 4000 to 1 per 1330

Note: these likelihoods are based on persons with age ranging from 0 yrs to 80 yrs. The study population persons are 45 yr to 70 years old. This implicates that the above mentioned likelihoods may be reduced with approximately 50%.

Side-effects related to the use of X-ray contrast.
Severe: 0.01 : 0.22% (severe allergic reaction with shock)
Total: 1.2 - 2.1% (flush, urticaria etc)

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

- cardiac asymptomatic patients at high-risk of cardiovascular disease,
- high-risk defined as having:
1. familial hypercholesterolaemia (FH)
2. diabetes mellitus, which is defined as
Whole blood Plasma
Fasting or >= 6.1 (>= 110) >= 7.0 (>= 126)
2-h post glucose load >= 10 (>= 180) >= 11.1 (>= 200)
3. peripheral vascular disease
- age 45-70 years except for men with FH -40 years;Additional specific MSCT criterium: stable heart rate

Exclusion criteria

Exclusion criteria
- Known CAD
- Refractory ventricular arrhythmia
- Other serious medical illness
- Participation in other study
- Additional specific MSCT criteria:
o Renal dysfunction (serum creatinine) > 120 mml/L
o Contrast allergy (hypersensitivity)
o Irregular heart rhythm (atrial fibrillation)
o Fast heart rate (> 75 bpm)
o Severe COPD
o Contra-indication against β-blockade
o Hypotension (<= 90 mmHg)
o Bronchospasm
o Severe LV dysfunction
o Pregnancy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-01-2008
Enrollment:	1000
Type:	Actual

Ethics review

Approved WMO Date:	08-01-2008
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-02-2014
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	NL16994.078.07