Modification of Cardiovascular Risk and Management with MSCT coronary imaging

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To demonstrate whether the use of MSCT in addition to traditional risk assessment may improve risk stratification in patients presenting without typical complaints for CAD but an elevated risk profile.

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

Summary

ID

NL-OMON31371

Source
ToetsingOnline

Brief title
MSCT to improve cardiovascular management

Condition

- Coronary artery disorders

Synonym
Atherosclerosis, coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Nederlandse Hartstichting

Intervention

Keyword: Cardiovascular diseases, imaging, Prevention

Outcome measures

Primary outcome

Primary endpoint

Cumulative cardiac death, myocard infarct, unstable angina requiring hospitalization and stroke, during a follow-up period of 5 years.

The primary endpoint will be compared against an age and gender matched cohort based on a validated computer simulation (based on Rotterdam Study, SCORE, Framingham).

Secondary outcome

1. Proportion of patients with MSCT calcium scores <10, 10-400, >400 (Agatston).

2. Proportion of patients reclassified using MSCT as low, intermediate, high or very high risk.

3. Reduction of adverse events during 5-year follow-up using MSCT risk stratification as compared to risk stratification without MSCT

4. Estimated net costs savings during 5-year follow-up using MSCT risk stratification as compared to risk stratification without MSCT

5. Cost-effectiveness of MSCT risk stratification as compared to risk stratification without MSCT

Study description

Background summary

Acute cardiac death or nonfatal myocardial infarction is the first clinical manifestation of coronary atherosclerosis in 40-50% of cases. Eighty percent of coronary artery disease (CAD) mortality in individuals <65 years occurs during the first heart attack. Moreover, 57% of men and 64% of women who died suddenly of CAD had no previous symptoms that were typical for the presence of CAD. Traditional risk factors are used to define the statistical likelihood of development of an adverse coronary event, but they cannot provide direct evidence of the presence or degree of coronary atherosclerosis. Accordingly, traditional riskfactors are not exact predictors of risk and more refined methods are needed. Knowledge of the presence of atherosclerosis would be most benificial for this purpose and would allow more appropriate risk stratification. Since recently, direct visualization of atherosclerosis in a non-invasive and patient-friendly manner has become possible with MSCT scanning. Accordingly, the use of MSCT may improve risk stratification by identification of those patients with and without atherosclerosis. By determining the various degrees of subclinical atherosclerosis, a more precise reclassification of high-risk patients into low, medium, high or very high-risk groups. This reclassification may then allow tailoring of risk management and improve cost-effectiveness.

Study objective

To demonstrate whether the use of MSCT in addition to traditional risk assessment may improve risk stratification in patients presenting without typical complaints for CAD but an elevated risk profile.

Study design

prospective study

Study burden and risks

Radiation burden
- calcium scan 1.3 to 2.0 mSv
- CT contrast scan 10-15 mSv

Side-effects contrast agent
- a severe side-effect occurs in 0.01% to 0.22% of all examinations.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Inclusion criteria:
Patients
- without symptoms typical for CAD,
- 45-70 years of age and
- at high-risk for cardiovascular events, defined as having: a >10% risk on cardiovascular mortality and morbidity according to SCORE adjusted for the Netherlands, or diabetes mellitus.
- Stable heart rate as a prerequisite for MSCT

Exclusion criteria

-Known CAD
- Ventricular arrhythmia
- Other serious medical illness
- Participation in other study

- Additional specific MSCT criteria
1. Renal dysfunction (defined as serum creatinine > 120 mmol/L
2. Contrast allergy
3. Irregular heart rhythm
4. Fast heart rate in combination with contra-indications against beta-blocking medication
5. Pregnancy

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	450
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL18234.058.07