Diagnostic accuracy of spectral computed tomography for detection of flow limiting coronary stenosis using fractional flow reserve as the standard of reference

Published: 29-06-2016
Last updated: 17-04-2024

The overall objective of this project is to assess the accuracy of SDCT for the detection of flow limiting stenosis in the coronary arteries using invasive FFR as the standard of reference. Whereby different subaims (e.g. improvement of FFRCT) are...

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

Summary

ID

NL-OMON47021

Source
ToetsingOnline

Brief title
CLARITY study

Condition

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

Synonym
coronary stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Coronary artery disease, Coronary stenosis, Fractional Flow Reserve, Myocardial, Spectral computed tomography

Outcome measures

Primary outcome

The main study parameters are SDCT and invasively measured FFR. The main endpoints is sensitivity and specificity of SDCT for the detection of hemodynamically significant coronary artery stenosis defined as FFR <0.8. To determine the main endpoints, our study is divided in different aims. For each aim, different factors, whether or not combined together, are used to assess (improvement of) the main study endpoints. These factors are:

• Improved definition of coronary anatomy by reducing blooming of calcifications

• FFRCT

• Myocardial iodine distribution

• Dynamic mycocardial perfusion

Secondary outcome

Secondary study parameters and endpoints are degree of calcium blooming and beam-hardening artifacts. A third parameter and endpoint is myocardial blood volume quantification.

Study description

Background summary

Cardiovascular disease remains the leading cause of morbidity and mortality worldwide. Coronary computed tomography angiography (CCTA) and, if indicated, invasively measured fractional flow reserve (FFR) is currently used for ruling out significant coronary artery disease. FFRCT is a novel non-invasive technique in which FFR is derived from CT images, however this method is currently, just like CCTA, lacking specificity. Spectral Detector CT (SDCT) is a novel technique whereby a spectrum of monoenergetic images at different keV values (40 to 140keV) can be reconstructed. By using these monoenergetic images, tissue decomposition is possible and a decrease in blooming and beam-hardening artifacts could be achieved. In addition, SDCT offers the opportunity to assess myocardial iodine distribution and quantification. When combining these factors, we hypothesize more accurate information will be available about the coronary anatomy, degree of stenosis and FFRCT and thereby contribute to a more accurate way for the detection of hemodynamic significant stenosis. Therefore the aim of this study is to assess the accuracy of SDCT as a non-invasive way for the detection of hemodynamically significant coronary artery stenosis.

Study objective

The overall objective of this project is to assess the accuracy of SDCT for the detection of flow limiting stenosis in the coronary arteries using invasive FFR as the standard of reference. Whereby different subaims (e.g. improvement of FFRCT) are made to answer the overall objective. The second objective is to determine the decrease of blooming of calcifications and beam-hardening artifacts and the improvement of myocardial blood volume quantification on SDCT in comparison with conventional CT.

Study design

Prospective observational diagnostic mono-center study.

Study burden and risks

The patient will not benefit from participating in this study and will receive routine care and an additional SDCT scan for research purposes. This study aims to contribute to a non-invasive way of measuring hemodynamic significance in coronary artery stenosis in future patients. The risks of this study are low. The procedures performed are safe, with a small risk for side effects and/or allergic reaction to adenisone, beta blockers, nitroglycerin and contrast agent. The estimated extra radiation dose is below 10 mSv. Combined with the clinically performed FFR measurement it is estimated to be 9-18 mSv. The (long term) side effects of this amount of extra radiation are thought to be small. This study has been assessed by the radiation safety committee. The burden for

the subjects is little: a few scans in one session, which will take <=30 min.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- >=18 years old;
- Suspected or known stable angina with pre-test likelihood of 50-85% using the method recommended by the European Society of Cardiology 2013 Guidelines on the management of stable coronary artery disease (Eur Heart J 2013);
- Referred for invasive testing with fractional flow reserve;
- Willing and able to give informed consent.

Exclusion criteria

- Subjects with suspected or known stable angina with pre-test likelihood of 0-50% using the method recommended by the European Society of Cardiology 2013 Guidelines on the management of stable coronary artery disease (Eur Heart J 2013);
- Subjects who because of age, general medical or psychiatric condition, or physiologic status cannot give valid informed consent or tolerate the coronary CTA examination;
- Subjects with (severe) renal insufficiency, indicated as glomerular filtration rate (GFR) <60 ml/min;
- Subjects with unknown GFR or obtained >3 months before the planned scan;
- Contraindication or allergy to intravenous contrast agent(s);
- Subjects who participate in an other study with radiation which is estimated to be in risk category III (ICRP 62);
- Subjects who are pregnant;
- Subjects with contraindications to cardiac CT and/or step and shoot protocol, betablockers, adenosine or nitroglycerine.

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):	29-03-2017
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Date:	29-06-2016

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-10-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-06-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL55917.041.16