Assessment of coronary stent patency by photon counting CT

Published: 24-04-2023
Last updated: 07-04-2024

To assess the diagnostic performance of PCCT to identify the luminal patency compared with ICA as the reference standard, in patients with a history of PCI with stent placement and to assess image quality by applying different image reconstruction...

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

Summary

ID

NL-OMON53948

Source
ToetsingOnline

Brief title
PCCT stent patency assessment

Condition

- Coronary artery disorders

Synonym
Coronary stenoses ; artery narrowing

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: Coronary stenoses, Photon Counting CT, stent patency assessment

Outcome measures

Primary outcome

The main study endpoint is the diagnostic performance, including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV), of the PCCT for determining luminal patency of the coronary stent with ICA as the reference standard.

Luminal patency is defined as no more than 50% loss of the in-stent vessel lumen diameter on ICA.

Secondary outcome

Image quality score of the different reconstructions.

Study description

Background summary

Computed tomography (CT) is routinely used to non-invasively visualize and assess coronary arteries for presence of atherosclerosis. Coronary stenoses are often treated by percutaneous coronary intervention (PCI) including placement of a stent in the affected coronary artery. If after coronary stenting, the patient has recurrent angina, this may be due to in-stent restenosis.

Although assessment of coronary stent patency is possible to a certain degree with current CT scanners it is still hampered by technical limitations of the scanner, the lack of sufficient spatial resolution to visualize the small stent diameter as well as blooming artefacts generated by the stent metal. In the clinical setting, in-stent restenosis (ISR) is one of the main long-term complications after coronary stent placement. This results in the routine use of invasive coronary angiography (ICA) to determine stent patency.

The use of ICA comes along with complications of the invasive procedure. To determine stent patency by CT identifying the vessel lumen within a fraction of a millimeter, and thus a much higher spatial resolution is required. Photon Counting CT (PCCT) is a completely new technique that offers specific advantages over the currently available city systems.

PCCT uses photon-counting detectors, which can overcome some of the technical shortcomings associated with CCTA. PCCT offers an improvement in spatial resolution up to a factor of three and furthermore eliminates electronic noise which greatly improves image quality.

At Erasmus MC, one of the world's first commercially available photon counting CT scanners has been installed that is cleared for clinical use.

Given the improvements in spatial resolution with photon counting CT we expect that noninvasive determination of coronary stent patency with PCCT will be possible with a higher sensitivity and specificity than before.

Study objective

To assess the diagnostic performance of PCCT to identify the luminal patency compared with ICA as the reference standard, in patients with a history of PCI with stent placement and to assess image quality by applying different image reconstruction techniques.

Study design

This study is a prospective, single-centre study.

Study burden and risks

Participants in this study gain no direct individual benefit from participation. The knowledge gained will be incorporated in the optimization of PCCT scan. This will be of benefit for other patients that will have to undergo CT scanning in the future.

Potentially patients participating in the current study may have to undergo repeat imaging to determine stent patency. If this is the case, they might benefit from the knowledge gained in the current study.

There is a risk associated with the performance of the photon counting CT scan due to administration of additional radiation dose and contrast material.

The benefit of this research project, which is an increase in knowledge leading to health benefit, justifies the additional radiation risk of the order of one in a hundred thousand, corresponding to an effective dose of 6 mSv for a normal

average adult. In clinical routine iodinated contrast material is considered to be safe to administer up to 2 millilitres per kilogram of body weight.

Participants in this study will not be exposed to a total iodinated intravenous contrast dose of more than this threshold. Additionally, there is the risk of an allergic reaction to iodinated contrast material. Therefore, patients that have a known contrast allergy cannot participate. Since intravenous iodinated contrast material administration may decrease renal function, we will not include patients with an eGFR of less than 30 ml/min/1.73m2. Therefore, we feel the additional risk of iodinated contrast material administration with regard to a decrease in renal function to be very low.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age >= 18 years
- History of PCI with coronary stent placement
- Referred for clinically indicated non-emergent ICA

Exclusion criteria

- Patient not meeting inclusion criteria
- (possible) pregnancy
- Concomitant or previous participation in a study that prohibits the patient from participating in a study that exposes the patient to radiation
- eGFR <30 ml/min/1.73m2
- Allergy to iodinated contrast material
- Inability to provide informed consent

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	30-12-2022
Enrollment:	138
Type:	Anticipated

Medical products/devices used

Generic name:	Full body Foton Counting CT-system. NAEOTOM Alpha syngo CT VA40
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	24-04-2023
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	07-02-2024
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	NL82713.078.22