Defining the Diagnostic Value of High-Pitch CCTA and Dynamic CT Perfusion in patients with prior PCI for the Diagnosis of Myocardial Ischemia as Defined by Invasive Flow and Pressure Indices - The PACIFIC-III trial

Published: 22-06-2021
Last updated: 04-04-2024

To determine the diagnostic performance of high-pitch CCTA and dynamic CTP for the diagnosis of myocardial ischemia using invasive coronary indices as the reference standard.

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

Summary

ID

NL-OMON50843

Source
ToetsingOnline

Brief title
The PACIFIC-III trial

Condition

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

Synonym
arteriosclerosis, Coronary artery disease

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Computed tomography angiography, Computed tomography Perfusion, Coronary artery disease, FFR

Outcome measures

Primary outcome

To assess the diagnostic performance in terms of sensitivity, specificity,

negative predictive value (NPV), positive predictive value (PPV) and diagnostic

accuracy of high-pitch CCTA and dynamic CTP for the diagnosis of significant

CAD as defined by an FFR <=0.80 in patients with a history of CAD.

Secondary outcome

(1) To compare the diagnostic capabilities of high pitch CCTA and dynamic CTP

to detect significant CAD when defined by instantaneous wave-free ratio (iFR).

(2) To investigate the potential of high-pitch CCTA to improve plaque

characterization and as such diagnosis of ischemia - due to mounting evidence

suggesting a relationship between adverse plaque characteristics and ischemia -

and prognosis.

(3) To evaluate the prognostic value of high-pitch CCTA and dynamic CTP.

Study description

Background summary

Recent development in computed tomography (CT) hardware have fulfilled the prerequisites for clinical CT myocardial perfusion imaging (CTP). Cardiac CT, has by means of coronary computed tomography angiography (CCTA) and novel techniques such as CTP the unique ability to provide information on both the anatomical and functional severity of coronary artery disease (CAD). However, diagnostic performance of these novel techniques when referenced by the clinical diagnostic standard, invasive fractional flow reserve (FFR) measurements, has scarcely been investigated in patients with a prior PCI for stable CAD.

Study objective

To determine the diagnostic performance of high-pitch CCTA and dynamic CTP for the diagnosis of myocardial ischemia using invasive coronary indices as the reference standard.

Study design

The study is a single-center prospective comparative trial in which all patients will undergo high-pitch CCTA and dynamic CTP before invasive coronary angiography (ICA) in conjunction with invasive flow/pressure measurements.

Study burden and risks

A two day protocol will be completed after referral ensuring the diagnostic work-up of patients is not delayed. On day 1 patients will undergo CCTA and CTP. Then, on day 2, irrespective of CT results, patients will undergo ICA with invasive pressure measurements. The risks of CT are considered to be low. Patients are referred for a clinically indicated ICA and as such risks of the ICA are not deemed study-related. However, CCTA and dynamic CTP imaging require radiation. The estimated combined radiation dose for CCTA and dynamic CTP will be ~12-13 mSv. Also, Dynamic CTP and CCTA require the use of iodinated contrast. Reactions to contrast material may occur. Overall, the reported incidence of adverse events with low-osmolar iodinated contrast is 1.5 events per 1000 doses (2.62% of which are serious). Patients are referred for a clinically indicated ICA and as such risks of the ICA are not deemed study-related. Regarding the CCTA, patients with a heart rate above 65 per minute can be given metoprolol. Side effects of this are low blood pressure and dizziness. Nitroglycerin is also given before the CCTA. This can cause a headache. Adenosine is given prior o the CTP. Side effects of this are rhythm disturbances (including AV block) and skips.

Future patients might benefit from the present study as combined anatomical information (CCTA) and functional information (dynamic CTP) obtained within one scan-protocol might lead to a more judicious referral for ICA which leads to a reduction of exposure to the possible unnecessary risk of an invasive procedure. In addition, CT is a cost-effective technique in comparison with invasive coronary angiography. Cardiac CT as a non-stop-shop will allow all centers to perform anatomical and perfusion imaging in one session and will spare patients to be referred to tertiary centers for state-of-the-art imaging.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1117
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- History of PCI for stable CAD
- Referred for a diagnostic ICA.

- Age above 35 years.

Exclusion criteria

- History of severe COPD or chronic asthma
- Pregnancy
- Renal failure (eGFR <30 mL/min)
- Use of sildenafil (Viagra) or dipyramidol (Persantin) that cannot be terminated
- Contra-indications for β-blockers
- Allergic reaction to iodized contrast
- Concurrent or prior (within last 30 days) participation in other research studies using investigational drugs
- Claustrophobia
- Significant co-morbidities
- Atrial fibrillation, second or third degree atrioventricular block
- Tachycardia
- Acute myocardial infarction (STEMI/NSTEMI)
- History of CABG
- Patients with a history of coronary chronic total occlusion
- LVEF estimated <50%
- Cardiomyopathies
- Previous radiation exposure in the diagnostic work-up
- Unable to give informed consent
- Indispensable follow-up with (serial) CT scans for non-cardiac related condition

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2021

Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	22-06-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	29-10-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL76256.029.21