Physiologic Assessment of Coronary Stenosis Following PCI

Published: 23-10-2017
Last updated: 12-04-2024

Determine the range of post-PCI iFR and the rate of significant residual ischemia defined as iFR

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

Summary

ID

NL-OMON45522

Source
ToetsingOnline

Brief title
DEFINE PCI

Condition

- Coronary artery disorders

Synonym
blockage in heart artery, coronary stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Philips Volcano
Source(s) of monetary or material Support: Philips Volcano;opdrachtgever

Intervention

Keyword: coronary stenosis, iFR, post-PCI iFR

Outcome measures

Primary outcome

Rate of residual ischemia defined as iFR <0.90 after operator-assessed angiographically successful PCI (residual diameter stenosis <50% in any treated lesion in the target vessel)

Secondary outcome

Secondary clinical endpoints:

1. Composite of cardiac death, target vessel myocardial infarction, ischemia-driven target vessel revascularization or recurrent ischemia at one year (definition below)
2. Target vessel failure defined as cardiac death, target vessel myocardial infarction, ischemia-driven target vessel revascularization
3. Quality of life (assessed by the Seattle Angina Questionnaire) at baseline, 30-days, 6 months and 1year
4. All-cause and cardiac mortality at one year
5. Target vessel Myocardial infarction at one year
6. Ischemia-driven target vessel revascularization at one year
7. Recurrent ischemia at one-year

Secondary physiology endpoints:

8. Correlation between iFR <0.90 and coronary stenosis >50% assessed by visual interpretation
9. Proportion of cases in which the iFR would become non-significant if a focal

stenosis demonstrated by iFR pullback were treated with PCI

10. Differentiation of the cause for impaired iFR (categorized as stent

related, distant focal stenosis, or diffuse atherosclerosis)

11. Predictors of delta iFR before and after PCI

Study description

Background summary

Numerous studies of coronary stenting over the past decade have consistently demonstrated that recurrent episodes of angina within the first year post PCI are common, occurring in approximately 20% of patients. This may lead to a substantial increase in repeat invasive procedures and associated health care costs.
Physiologic assessment of coronary stenoses prior to percutaneous coronary intervention (PCI) is superior to coronary angiography alone for lesion evaluation, reducing overall major cardiac events as well as cost. However, data on post PCI physiology is scarce and thus rarely used in clinical practice. Limited clinical data on post PCI Fractional Flow Reserve (FFR) and instantaneous wave-free ratio (iFR) indicate that a substantial number of patients (up to 20%) have impaired coronary physiology at the completion of the procedure despite an angiographically successful PCI. It is not known whether an abnormal post-PCI FFR or iFR is predictive of recurrent angina and whether the routine use of physiological indices of coronary function can predict future cardiovascular events.
iFR safely and accurately quantifies stenosis severity in a wide range of lesions and may be helpful in assessing post PCI physiology. Compared with FFR, it allows rapid assessment of the lesion without induction of maximal hyperemia with adenosine. iFR pullback has the potential additional advantage of interrogating the entire coronary artery to identify culprit lesions with significant pressures gradients.

Study objective

Determine the range of post-PCI iFR and the rate of significant residual ischemia defined as iFR <0.90 following operator-assessed angiographically successful PCI

Study design

DEFINE-PCI is a multi-center, prospective, observational study in up to 25

centers in USA and internationally. Consented subjects with CAD who undergo physiologic lesion assessment with iFR<0.90 in at least 1 coronary artery are eligible for participation. After successful PCI to all culprit lesions based on angiographic assessment of the treating physician, a blinded post-PCI iFR and iFR pullback will be performed. The proportion of patients with impaired post-PCI iFR will be assessed, and the number of patients in whom ischemia could theoretically be normalized with further PCI determined. Additionally, the association between the post-PCI iFR results and cardiovascular events and clinical symptoms will be assessed. Follow-up will be at 1, 6 and 12 months, including administration of quality of life questionnaires.

Study burden and risks

As part of this study patients will be undergoing the following assessments in addition to the normal treatment:
-an additional IFR measurement of the treated coronary arteries after PCI.
-4-8h after PCI a single blood sample will be drawn for the determination of cardiac biomarkers.
-after 1, 6 and 12 months, the patient will be contacted by telephone to assess events and medication.
-each visit a questionnaire will be completed/ filled in by the patient.

The duration of the procedure is extended by the additional IFR measurement. The extra time may vary from 5 minutes to half an hour, depending on the number of vessels that is measured.

Contacts

Public
Philips Volcano

Excelsiorlaan 41
Zaventem 1930
NL
Scientific
Philips Volcano

Excelsiorlaan 41
Zaventem 1930
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1.Subject must be > 18 years old
2.Subjects presenting with stable angina, silent ischemia or non-ST-elevation ACS (unstable angina or biomarker positive)
3.Single vessel CAD with at least 2 separate lesions (*10 mm apart) of *40% stenosis or a single long lesion of *20mm OR multi-vessel CAD, defined as at least 2 vessels with *40% stenosis
4.Pre-PCI iFR performed in all vessels intended for PCI
5.Pre-PCI iFR of <0.90 of at least 1 stenosis
6.Subjects are able and willing to comply with scheduled visits and tests and to provide informed consent.

Exclusion criteria

1.Pregnant or planning to become pregnant for the duration of the study
2.Acute STEMI within the past 7 days
3.Cardiogenic shock (sustained (>10 min) systolic blood pressure < 90 mmHg in absence of inotropic support or the presence of an intra-aortic balloon pump).
4.Ionotropic or temporary pacing requirement
5.Sustained ventricular arrhythmias
6.Prior CABG
7.Known ejection fraction *30%
8.Chronic Total Occlusion (CTO)
9.Known severe mitral or aortic stenosis.
10.Any known medical comorbidity resulting in life expectancy < 12 months.
11.Participation in any investigational study that has not yet reached its primary endpoint.
12.Known severe renal insufficiency (eGFR <30 ml/min/1.72 m2).
13.TIMI flow <3 at baseline

14.Intra-coronary thrombus on baseline angiography

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-12-2018
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	23-10-2017
Application type:	First submission
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
ClinicalTrials.gov	NCT03084367
CCMO	NL61437.029.17