Physiology and Imaging Pre- and Post Stenting 2

Published: 22-09-2017
Last updated: 12-04-2024

This study aims to determine the percentage of changes in decision making regarding sizing and optimization of apposition of the magnesium scaffold as a result of OCT imaging before and after implantation of the scaffold compared to an angiographic...

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

Summary

ID

NL-OMON45423

Source
ToetsingOnline

Brief title
PIPPS 2

Condition

- Coronary artery disorders

Synonym
arteriosclerosis, atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Catharina-ziekenhuis
Source(s) of monetary or material Support: Biotronik,PIPPS2 is investigator initiated;maar ontvangt een unrestricted research grant van Biotronik

Intervention

Keyword: coronary intervention, intracoronary imaging, intracoronary physiology, magnesium scaffold

Outcome measures

Primary outcome

Primary objectives:

- Percentage of cases in which changes are made in selecting stent size and

length after the initial OCT run compared to an angiographic based strategy.

- Percentage of cases in which changes are made in post-stenting strategy after

the final OCT run compared to an angiographic based strategy.

Secondary outcome

Secondary objectives:

- Fractional flow reserve (FFR) measured before and after placement of the

Magnesium biodegradable stent, to determine to what extend FFR is influenced by

the presence of the stent in the vessel segment.

- the occurence of cardiac events after 6 and 12 months follow up.

Study description

Background summary

Since the first use of drug eluting stents in coronary arteries, the risk of restenosis and stent thrombosis has been dramatically decreased. However, the permanent presence of metal struts in the arterial wall is believed to be disadvantageous regarding thrombus formation, as well as impairment of endothelial response and vasomotive aspects that are lost once the intima is covered in metal struts. A bioresorbable drug eluting stent would overcome these advantages e.g. the magmaris stent.
However, another reason for thrombus formation is the malapposition of a stent due to undersizing or inadequate deployment which often not obvious from the

angiogram and becomes apparent with the use of optical coherence tomography (OCT). This malapposition will have an effect of the hemodynamic profile of the stent especially in these biodegradable stents which have larger strut thickness compared to the metal stents.
This study aims to determine the percentage of changes in decision making regarding sizing and optimization of apposition of the Magmaris magnesium scaffold as a result of OCT imaging before and after implantation of the scaffold in comparison to angiographic sizing. FFR measurement adds functional information to these anatomical parameters.

Study objective

This study aims to determine the percentage of changes in decision making regarding sizing and optimization of apposition of the magnesium scaffold as a result of OCT imaging before and after implantation of the scaffold compared to an angiographic based strategy. FFR measurement adds functional information to these anatomical parameters.

Study design

Prospective observational design.

Study burden and risks

There is no additional risk for the patient when participating in this study.
All treatment modalities are standard equipment in the cathlab. FFR is used in most PCI cases in the cathlab, it has a Class 1A recommendation for lesion analysis pre-PCI in the European Society of Cardiology guidelines for revascularization8. Use of OCT is strongly recommended when placing a biodegradable stent and thus can be considered standard of care. Potential benefit derives from the use of state of the state of the art biodegradable stent combined with the use of FFR and OCT. Risks related to FFR or OCT are low and almost always temporary.

Contacts

Public
Catharina-ziekenhuis

Michelangolaan 2
Eindhoven 5623 EJ
NL
Scientific
Catharina-ziekenhuis

Michelangolaan 2
Eindhoven 5623 EJ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In this study, patients from 18 years are eligible for inclusion if they are scheduled for PCI.
De-novo lesions in a 3,0-3,5 mm artery up to 25mm are suitable to be treated.
All patients have to be able to give written informed consent.

Exclusion criteria

- patients < 18 years
- Cardiogenic shock
- severe calcification or chronic occluded artery.
- bifurcation lesions
- previous bypass surgery
- pregnancy
- inability to give informed consent
- contra-indication for adenosine infusion such as allergy.

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):	15-05-2018
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	22-09-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL60386.100.17