Revascularization with paclitaxel-coated balloon angioplasty versus drug-eluting stenting in acute myocardial infarction - a randomized controlled trial

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

Summary

ID

NL-OMON41152

Source
ToetsingOnline

Brief title
REVELATION

Condition

- Coronary artery disorders

Synonym
acute myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis

Source(s) of monetary or material Support: Biotronik,research grant,Volcano

Intervention

Keyword: acute myocardial infarction, drug-eluting balloon, drug-eluting stent

Outcome measures

Primary outcome

The primary endpoint is fractional flow reserve (FFR) at 9 months angiographic follow-up. FFR is the ratio of mean coronary pressure distal of the treated lesion to mean aortic pressure during maximum hyperemia.

Secondary outcome

Angiographic endpoints:

- Instantaneous wave-free ratio (iFR)

- TIMI coronary flow

- laesion specific aspects

STsegment resolution on ECG

Clinical endpoints

- MACE: major adverse coronary events, such as cardiac death, recurrent myocardial infarction in treated vessel, recurrent revasularization of infarct-related laesion

- stent thrombosis

- major bleedings

Study description

Background summary

Compared with balloon angioplasty, implantation of bare metal stents (BMS) and drug eluting stents (DES) have shown to reduce repeat target lesion revascularization in primary percutaneous coronary intervention (PPCI). However, this did not result in a reduction of mortality or recurrent myocardial infarction. Furthermore, there are concerns of the occurrence of stent thrombosis. The PAPPA-pilot study, evaluating safety and feasibility of using a drug-eluting balloon (DEB) only strategy in PPCI, showed good short- and long-term clinical results, with sustained safety and efficacy at 12 months follow-up. To date little is known about the long-term effects of this treatment modality in STEMI. Besides, angiographic follow-up is of great clinical importance by giving insight on the treated infarct lesion and to assess the functional angioplasty result.

Study objective

This randomized controlled trial is designed to prospectively assess the safety and efficacy of a CE-marked paclitaxel-eluting balloon only strategy versus third generation DES in the setting of a STEMI. This inferiority design serves to demonstrate this comparison in terms of fractional flow reserve at 9 months angiographic follow-up, as a functional assessment of the angioplasty result.

Study design

This study is a prospective, single center, randomized controlled trial. A group of 120 patients will be enrolled in this study. Randomization will be done by 1:1 ratio. No cross-over between the 2 arms will be accepted.

Intervention

All procedures will be performed by an interventional cardiologist. The use of thrombectomy or thrombosuction devices is recommended as a standard procedure in STEMI. Predilatation with a balloon is mandatory. Overall it is recommended to achieve an optimal lumen diameter by predilatation.
In case of randomization to the DEB only strategy, the DEB is deployed at low pressure (max 10 atm) for at least 60 seconds, and the diameter has a 1:1 balloon-to-artery ratio. As current standard of care, provisional stenting in case of a DEB only strategy is at the discretion of the operator and advised only in case of:
• Residual minimal luminal diameter of the treated lesion < 50% after balloon dilatation(s) with sufficiently large balloon;
• Dissections >= type C, leading to (threatening) vessel closure

In case of additional stenting, a BMS must be used.
DES implantation following current guidelines.
The use of medication is according current guidelines, including one year of dual anti-platelet therapy for all patients.

Study burden and risks

The initial procedure en hospitalization will be performed according to accepted guidelines and current standard of care. No benefits or additional risks are expected. The burden for the control coronary angiography is limited. Patients need to come to the hospital on an outpatient basis for one day. Costs for travelling to the hospital will be compensated. The patient will be accompanied by one of the research nurses during all investigations. Besides this, the patient will be contacted by telephone only 5 times during 5 year of follow-up. These conversations will be around 10 minutes and wil contain questions about his/her medical status.
The main risk and complications of the study are associated with the control coronary angiography. These are all discussed with the patient at the time of recruitment. The risk of a severe complication at cardiac catheterisation is around 0.03%.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All patients presenting with an acute ST-elevation myocardial infarction and suitable for primary percutaneous coronary intervention(PPCI). The protocol requires visualization, thrombus aspiration and pre-dilatation of the culprit lesion before inclusion.;Acute myocardial infarction eligible for PPCI:
• > 20 min of chest-pain and at least 1 mm ST-elevation in at least two contiguous leads, a new left bundle branch block or a true posterior myocardial infarction (confirmed by ECG or echocardiography)
• reperfusion is expected to be feasible within 12 hours after onset of complaints
Infarct related artery eligible for PPCI and:
• De novo lesion in a native coronary artery
• Reference-vessel diameter >= 2.5mm and <= 4mm
• Without severe calcification
• Without diameter stenosis of >50% (by visual assessment) after thrombus aspiration and pre-dilatation.

Exclusion criteria

• Age < 18 years and > 75 years
• History of myocardial infarction
• Known contraindication/resistance for bivalirudin, fondaparinux, heparin, aspirin, prasugrel and/or ticagrelor.
• Participation in another clinical study, interfering with this protocol
• Uncertain neurological outcome e.g. resuscitation
• Intubation/ventilation
• Cardiogenic shock prior to randomization
• Known intracranial disease (mass, aneurysm, AVM, hemorrhagic CVA, ischemic CVA/TIA < 6 months prior to inclusion or ischemic CVA with permanent neurological deficit)
• Gastro-intestinal / urinary tract bleeding < 2 months prior to inclusion
• Refusal to receive blood transfusion
• Planned major surgery within 6 weeks
• Stent implantation < 1 month prior to inclusion
• Expected mortality from any cause within the next 12 months

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-09-2014
Enrollment:	120
Type:	Actual

Medical products/devices used

Generic name:	drug-coated balloon
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-06-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	07-09-2015
Application type:	Amendment
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	NL48495.100.14