PAclitaxel-eluting balloon in Primary PCI in Amsterdam: 1-year angiographic evaluation of target lesion patency.

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The PAPPA-trial was the first prospective clinical study the feasibility and safety of a DEB only strategy in PPCI for STEMI. One-year angiographic follow-up is warranted to evaluate long-term patency of the target lesion. So far there has not been...

Ethical review	Not approved
Status	Will not start
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON35497

Source
ToetsingOnline

Brief title
PAPPA-patency

Condition

- Coronary artery disorders
- Cardiac therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
coronary artery disease

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis

Source(s) of monetary or material Support: cardiologie researchfunding OLVG

Intervention

Keyword: Angiographic evaluation, Drug-eluting balloon, Paclitaxel-eluting balloon, Primary PCI

Outcome measures

Primary outcome

The primary angiographic endpoint to be evaluated is the late in-segment luminal loss as determined by laboratory measurement of the difference between the minimal lumen diameter (MLD) at follow-up catheterization and post-initial procedure.

Secondary outcome

Secondary endpoints include binary restenosis defined as >=50% diameter stenosis at follow-up, located within the target segment, respectively, and other angiographic results e.g. late occlusion.

Study description

Background summary

The use of bare-metal coronary stents (BMS) has shown to reduce the need for repeat target lesion revascularization (TLR) in patients treated with primary percutaneous coronary intervention (PPCI), compared with balloon angioplasty. However, in the setting of ST-segment elevation myocardial infarction (STEMI), the decrease in TLR did not result in a reduction of reinfarction and/or mortality rate. Studies evaluating the use of drug-eluting stents (DES) versus BMS in PPCI for STEMI have shown equal rates of mortality and reinfarction. Although the use of DES in PPCI patients has led to a reduction of TLR, there have been concerns about long-term delay of arterial healing and the associated risk of late stent thrombosis. As a novel treatment modality, a drug-eluting balloon (DEB) may be a therapeutic challenge in STEMI, as it can provide the potential advantage of delivering an anti-proliferative drug, thereby probably reducing TLR, without leaving a coronary stent. Therefore the *Paclitaxel-

eluting balloon in Primary PCI in Amsterdam (PAPPA)*-pilot evaluated the use a DEB only strategy in STEMI patients. Of 100 consecutive STEMI patients, 59 patients were treated with a DEB only strategy; bailout stenting was performed in 41 patients. All patients were treated with peri-and post-procedural i.v. bivalirudin, on top of a loading dose aspirin, heparin and prasugrel. One month follow-up was available for all patients. A total of 3 major adverse cardiac events (MACE) were reported within one-month follow-up, all events occurred in the DEB only group. The use of a CE-marked paclitaxel-eluting balloon in PPCI in patients with STEMI, combined with bivalirudin, appeared to be a safe treatment modality.

Study objective

The PAPPA-trial was the first prospective clinical study the feasibility and safety of a DEB only strategy in PPCI for STEMI. One-year angiographic follow-up is warranted to evaluate long-term patency of the target lesion. So far there has not been an angiographic follow-up of this specific treatment in PPCI-patients. Angiographic follow-up results after elective PCI with the use of DEB, in in-stent re-stenosis and small vessel disease, have shown sustained efficacy over a half to one year after application.

Study design

General: The original PAPPA-pilot is a prospective, single centre study. From November 2010 until April 2011, a total of 100 consecutive patients presenting with STEMI were enrolled in this study. Patients were treated with a paclitaxel-eluting balloon only strategy. Additional bare metal stenting was performed in case of a residual stenosis > 50% or coronary artery dissection type C to F.

Patient sample size: Considering loss to follow-up, repeat revascularization and refusal of informed consent for this study, we expect to enrol 50-75 patients for coronary angiography.

Duration: The study will start December 2011. With normal clinical practice in mind, not more than 2-3 diagnostic procedures can be performed every week in the OLVG. Patient inclusion is therefore assumed to take approximately 6 months.

Study schedule: The study assessments will be performed according to the following list:
Patient history - Clinical examination - Inclusion/exclusion criteria - ECG - Laboratory - Current medication
Exercise test - CAG - FFR/IVUS (if indicated)

Study documentation: The Investigator will be provided with an Investigator

File, which contains all documents relevant to the study. A CRF must be completed for all patients.

Study burden and risks

Admission to the hospital is indicated for 1 day. Al investigations will take place during this admission. No further follow-up is necessary. The risks of participation are listed in section E9.

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

- patients who are included in PAPPA-pilot (acute myocardial infarction presented for primary

PCI within 12h after onset symptoms and treated with a paclitaxel-eluting ballon and additionally stentplacement if indicated)
- patients understand the risk of coronary angiography and give written informed consent.

Exclusion criteria

- revascularization of target lesion by PCI or coronary artery bypass grafting.
- participation in another clinical study, interfering with this protocol.
- renal impairment at risk for contrast nephropathy, defined as creatinin > 130 mmol/L (or >1.47 mg/dl)
- the inability to provide written informed consent.
- initial angiography not suitable for quantitative coronary angiography (QCA).

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	75
Type:	Anticipated

Ethics review

Not approved

Date:	25-11-2011
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	NL38119.100.11