Drug Eluting Balloon in Acute Myocardial Infarction

Published: 18-11-2008
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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON35144

Source
ToetsingOnline

Brief title
DEB-AMI

Condition

- Coronary artery disorders

Synonym
coronary disease, myocardial infarction

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Myocardial infarction, PCI

Outcome measures

Primary outcome

Late loss of lumen diameter between index procedure and 6 month angiographic

follow-up.

Secondary outcome

1) Binary restenosis (> 50 %) at 6 month follow*up

2) Stent malapposition at 6 month follow*up

3) Endothelial dysfunction at 6 month follow*up

4) Clinical outcome at 1 and 5 year follow*up

Study description

Background summary

Patients with an acute myocardial infarction (AMI) are currently being treated with percutaneous coronary intervention (PCI) with placement of one ore more stents into the coronary vessel. A stent is a thin metal device, pre-mounted on a balloon. At the site of the stenosis the balloon is temporarily inflated which results in expansion and placement of the stent against the vessel wall. Within a couple of months the inner side of bare metal stents (BMS) is re-endothelialized. Unfortunately, in 10-25 % of cases there is an exaggerated reaction of neointimal growth resulting in re-stenosis of the stent. The currently wide used drug eluting stent (DES) have a medical coating to prevent exaggerated neo-intimal growth. However this can lead to a delayed and incomplete re-endothelialization of the stent. Malapposed and uncovered metal parts of DES are associated with an increased risk of late stent thrombosis and fatal or non-fatal AMI. Another disadvantage of the use of DES may be the negative effect on endothelial function in the distal coronary vessel due to the extended release of medication from the coated stent. An interesting new development is the drug eluting balloon (DEB) which allows a short period of delivery of medication (Paclitaxel) into the vessel wall. It has been hypothesized that the placement of BMS after DEB may prevent the risk of restenosis while allowing normal re-endothelialization of the BMS. Data from animals and patients with stable angina are encouraging. To our knowledge no studies with DEB have been performed in patients with AMI.

Study objective

The purpose of the study is to compare the combination of DEB/BMS versus DES versus BMS alone in patients with an AMI.

Study design

A total of 200 patients will be randomly allocated to one of three treatment arms. Randomisation will be blinded and performed via closed envelope. After 6 months all patients will undergo a control coronary angiography in order to evaluate the efficacy of the index treatment. In addition, 40 patients (10 of each group) will undergo optical coherence tomography (OCT) in order to evaluate stent endothelialization and malappostion, and acetylcholine derived evaluation of endothelial dysfunction.

Intervention

PCI is currently the standard treatment for patients with AMI. Several types of balloons and stents are being used. In the current study we will investigate different approaches of DEB and DES and BMS. Intra-coronary thrombo-suction prior to PCI is also a standard treatment in our center.

Study burden and risks

PCI with different types of balloons/stents is currently the treatment of choice in patients with AMI. In the current study a DEB is introduced prior BMS. The invasive treatment is not different as compared to standard PCI, except the 6 month angiographic follow-up. Due to the invasive nature of this investigation a small risk is involved. However these catheterizations are performed by high volume operators who do these procedures more than 300 times/ year. The potential advantage for patients is that they know the status of their coronary anatomy after 6 months and in case of a re stenosis a re-PCI can be performed immediately.

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

- Age: 18-80 year
- STEMI within 12 hours of onset of complaints
- Candidate for primary PCI with stent-implantation
- Successful thrombus aspiration defined by no angiographic signs of thrombus a the site of plaque rupture and TIMI flow * 1.

Exclusion criteria

- Unable to give written informed consent
- Previous PCI or CABG of infarct related vessel
- Left main stenosis * 50%.
- Severe triple vessel disease with stenosis * 50% in 3 epicardial coronary arteries.
- Target vessel reference diameter < 2.5 and > 4.0 mm
- Target lesion length < 25 mm
- Intolerance for aspirin or clopidogrel
- Life expentancy < 12 month

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-02-2009
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	Drug eluting stent and drug eluting balloon
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	18-11-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-01-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	02-03-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	

Date:	01-10-2010
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL24127.041.08