Randomized study to assess the effect of thrombus aspiration on flow area in STEMI patients: an Optical Frequency Domain Imaging (OFDI) study

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To evaluate whether primary percutaneous coronary intervention (primary PCI) with a new thrombectomy device as compared to primary PCI without thrombectomy increases minimal flow area after stenting for treatment of patients presenting with ST-...

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

Summary

ID

NL-OMON34145

Source
ToetsingOnline

Brief title
TROFI

Condition

- Coronary artery disorders

Synonym
Myoccardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Terumo

Source(s) of monetary or material Support: Medische Hulpmiddelen industrie

Intervention

Keyword: acute myocardial infarction, optical frequency domain Imaging, stenting, thrombus aspiration

Outcome measures

Primary outcome

Minimal Flow Area post-stenting assessed by OFDI

Secondary outcome

OFDI endpoint post procedure:

1. Minimal Flow Area post-stenting assessed by OFDI normalized for

observed/predicted stent area

OFDI endpoints post procedure and at 6-month:

2. Mean Flow area/volume

3. Intraluminal defect area/ volume

4. Mean Stent area/volume

5. Percent of malapposed struts

6. Incomplete Stent Apposition (ISA)area/volume

At 6 months, the following variables will be additionally assessed:

7. Percent of struts with coverage

8. Healing Index

9. Tissues prolapse area/volume

10. Procedure success (attainment of <30% residual stenosis of the target

lesion and no in-hospital MACE).

Safety endpoints:

11. Target Vessel Failure (TVF) defined as cardiac death, reinfarction in the territory of infarction related vessel (Q wave and non-Q wave), or clinically driven target vessel revascularization - and its individual components - at discharge, 1, month, 6, months and 12 months.

12. All-cause mortality, any myocardial infarction, target vessel revascularization.

13. Stent thrombosis according to ARC definition at discharge, at 1 month, 6 months and 12 months.

14. Other SAEs at discharge, 1 month, 6 months and 12 months.

Study description

Background summary

Primary percutaneous coronary intervention has been well established as the treatment of choice for the majority of patients presenting with Acute ST elevation myocardial infarction (STEMI). In fact primary PCI achieves better Thrombolysis in Myocardial Infarction (TIMI) 3 coronary flow grade and results in better ventricular preservation when compared to pharmacological thrombolysis. However primary PCI alone is unable to remove intracoronary thrombus and this often results in distal embolisation, no reflow which in turn leads to impaired myocardial perfusion. This can result in left ventricular dysfunction and subsequently increased mortality. Thrombus grade, a measure of thrombus load in patients
presenting with acute STEMI correlates with mortality and adverse cardiovascular events. The use of thrombectomy devices during PCI in the setting of acute ST elevation myocardial infarction has been recently shown to improve epicardial, myocardial perfusion, angiographical TIMI flow, blush score, or result in less embolisation. Moreover thrombus aspiration or rheolysis has been shown to decrease cardiac death and

repeat myocardial infarction.

On the other hand, the impact of thrombus on acute and chronic luminal dimension is still unclear in a setting of primary PCI. After stenting, such thrombus either:
I) protrude into the lumen through the mesh of metallic stent struts, or
II) is crushed between the vessel wall and stent.
Theoretically, the protruded thrombus can hinder the intra-luminal flow immediately after stenting, while the resorption of crushed thrombus against vessel wall might result at long term in stent malaposition. Due to the limited ability of the conventional angiography and
the intravascular ultrasound (IVUS) to detect thrombus, these aspects have not been investigated.

Optical coherence tomography has recently been shown to be feasible and to provide valuable information in the setting of acute myocardial infarction. This imaging modality has been shown to be even more sensitive to detect intraluminal mass (i.e. thrombus) and offers unique possibilities of analysis of coronary intervention in acute myocardial infarction.

Study objective

To evaluate whether primary percutaneous coronary intervention (primary PCI) with a new thrombectomy device as compared to primary PCI without thrombectomy increases minimal flow area after stenting for treatment of patients presenting with ST-segment elevation myocardial infarction (STEMI) as assessed by OFDI.

Study design

Prospective, randomized controlled, single blind, multicenter clinical study in 140 patients to show superiority of treatment with thrombectomy and Biolimus A9 drug-eluting stent [test] versus treatment with Biolimus A9 drug-eluting stent only (without thrombectomy) [comparator].
Eligible patients (STEMI <12 hours from onset of chest pain) will be randomized before the PCI in a 1:1 fashion to either primary PCI with thrombectomy or without thrombectomy. All patients will receive the Nobori® drug eluting stent and will undergo OFDI assessment of the culprit lesion immediately post-stent implantation.
All Patients will be followed clinically at 30 days, 6 and 12 months post-procedure.
Up to 40 patients in each arm (thrombectomy vs. non-thrombectomy) will undergo a repeat OFDI evaluation of the infarct culprit coronary artery at 6 months.

Intervention

OFDI Cathlab procedure

After stenting, patients will undergo the Optical Frequency Domain imaging. The imaging region will be defined based on angiographic landmarks, such as side branch take-offs, with a recommended length of 3-5 cm. The catheter and OFDI imaging system will be prepared as outlined in the respective instructions for use. All equipment to be used during the procedure will be carefully examined to ensure proper performance. Computer controlled, constant velocity pullback OFDI imaging will allow determination of the longitudinal position of the imaging catheter. Landmarks including the distal end of the guiding catheter and major side-branch vessels will be used to further improve registration accuracy.

Study burden and risks

With any percutaneous procedure there are risks and complications. However, the patients to be included in the study may be at greater risk as a result of their disease state and general health status. The risks will be evaluated on an individual basis and discussed with each Patient. This treatment may involve some additional risks to the study patient, the natures of which are unknown. Page 49 of the prococol includes an extensive list of anticipated adverse events that may result from the PCI procedure and imaging devices.
The occurrence of these complications may lead to the need for a repeat catheterization and/or PCI, myocardial infarction, emergency bypass surgery, or death. Since the OFDI catheters are investigational devices, risks associated with their use are not entirely known, but are believed to be similar to those that are associated with currently used IVUS catheters to image coronary artery.

It should be noted, however, that there are no foreseen increased risks to which subjects will be exposed by this study except extra catheters that will be introduced with possible standard risk of vessel damage. However, the risks described above will be minimized by selecting investigators qualified by training and experience to investigate the device and patients which comply with inclusion criteria. Each investigator will be trained in t he use of the devices prior to use.

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

1. Patient is at least 18 years of age
2. Patients with ST-segment elevation Myocardial Infarction documented in an ambulance or in a Cathlab, with >=2 mm ST segment elevation in at least two contiguous leads, presenting in the Cathlab <12 hours after the onset of symptoms lasting >=20 min and having an angiographically visible stenosis (>30%) or TIMI<= II in de-novo, native, previously unstented vessel
3. The single vessel coronary artery disease
4. Signed Informed Consent
5. The patient understands and accepts clinical follow-up and OFDI controls.
6. Patients residence is in the area covered by hospital
7.Vessel size should match available Nobori stent sizes (<4.0 mm, and >2.0 mm by visual assessment)

Exclusion criteria

1. Pregnancy
2. Known intolerance to aspirin, clopidogrel, heparin, stainless steel, Biolimus A9, contrast
3. Diameter Stenosis <30% in the target lesion
4. The multi-vessel coronary artery disease (DS>50%)
5. Unprotected left main coronary artery stenosis >30% by visual assessment
6. Distal vessel occlusion
7. Severe tortuous, calcified or angulated coronary anatomy of the study vessel that in the opinion of the investigator would result in sub-optimal imaging or excessive risk of

complication from placement of an OFDI catheter
8. Fibrinolysis prior to PCI
9. Known thrombocytopaenia (PLT< 100,000/mm3)
10. Contraindications to PCI, stenting, ASA, clopidogrel
11. Active bleeding or coagulopathy or patients at chronic anticoagulation therapy
12. Cardiogenic Shock
13. Significant comorbidities precluding clinical FU (as judged by investigators)
14. Major planned surgery that requires discontinuation of dual antiplatelet therapy
15. Proximal RCA stenosis (>30%) if the infarct-related artery is mid or distal-RCA

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-01-2011
Enrollment:	70
Type:	Actual

Medical products/devices used

Generic name:	Optical Frequency Domain Imaging (OFDI)
Registration:	No

Ethics review

Approved WMO

Date:	16-11-2010

Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL33330.078.10