RAndomized comParison between the STENTYS self-aPpOSIng Sirolimus-eluting Coronary STent and a balloon-expandable stent In AcuTe Myocardial InfarctiON

Published: 11-07-2012
Last updated: 26-04-2024

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

Summary

ID

NL-OMON37453

Source
ToetsingOnline

Brief title
Apposition IV

Condition

- Coronary artery disorders

Synonym
heart-attack, myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: Stentys
Source(s) of monetary or material Support: sponsor

Intervention

Keyword: myocardial infarction, self-expandable, stent

Outcome measures

Primary outcome

Percentage of stent strut malapposistie at 9 months, assessed by OCT.

Secondary outcome

OCT endpoint at 4 months:

1. Percentage of stent strut malapposistie

OCT endpoints at 4 or 9 months:

2. Percentage of bare stent struts

3. Healing Score

4. Mean Flow area / volume. (Average flow surface / volume)

5. Intraluminal defect area / volume. (Defective intraluminal surface / volume)

6. Mean stent area / volume. (Mean stent area / volume)

7. Incomplete Stent Apposition (ISA) area / volume (Incomplete stent apposition)

8. Tissue prolapse area / volume. (Surface tissue by the struts / volume)

Clinical secondary endpoints:

9. Procedure success: <30% residual stenosis of the target lesion and no MACE

during hospitalization (cardiac death, bypass surgery (CABG) or

revascularization (TLR, clinically driven) and non-fatal myocardial infarction).

10. MACE at 1, 4 / 9 and 12 months

11. Target Vessel Failure (TVF), defined as cardiac death, reinfarction in the area of **the infarct-related vessel (Q wave and non Q-wave according to ARC definition), or clinically driven revascularization of the vessel - and its individual components - for dismissal , 1, 4 / 9 and 12 months.

12. Any death, any myocardial infarction, target vessel revascularisation.

13. Stent thrombosis by ARC definition at discharge, at 1, 4 / 9 and 12 months.

14. All other SAEs at discharge, 1, 4 / 9 and 12 months.

Angiographic secondary endpoints:

15. In-stent and in-segment (5 mm proximal and distal margins of the stent) Minimum Lumen Diameter (MLD) at baseline and at 4 / 9 months.

16. In-stent and in-segment (5 mm proximal and distal margin of the stent) Percent diameter stenosis (% DS) at baseline and 4 / 9 months

17. Acute Gain (mm) post-stent procedure.

18. In-stent and in-segment (late) lumen loss at 4 / 9 months.

19. In-stent and in-segment binary restenosis (diameter stenosis >= 50%) on 4 / 9 months.

20. TIMI flow pre-and post-procedure and at follow-up.

21. TIMI (corrected) frame count post procedure.

22. Myocardial blush grade post-procedure.

ECG endpoint:

23. ST segment elevation resolution:% reduction of ST-segment elevation 90 ± 30

minutes after the procedure.

IMR endpoint:

24. Index of microvascular resistance (IMR Index of micro-vascular resistance)

post procedure (selected sites)

25. Percentage of patients with an IMR <= 32.

Study description

Background summary

Recently a new type of stent has been developed, the self-expandable Sirlimus-eluting Stentys-Stent. For placement of the stent, It is not necessary to use a balloon, thus reducing the chance of damaging the vessel wall, which is a risk when stents are placed using a balloon .. The stent slowly unfolds itself in the placement and settles against the wall to keep it open.

Study objective

The objective of this study is to evaluate whether two different stent technologies (a self-expandable stent and a balloon-expandable stent) may be associated with different stent strut apposition and a variety of stent strut coverage with endothelial tissue, evaluated by intra-coronary OCT 4 or 9 months (depending on randomization) post-stent implantation.

Study design

This is a prospective, multicenter, randomized study in which 150 patients will participate in about 20 European hospitals

Intervention

Two treatment groups will be assessed:
- STENTYS DES (S) self-expandable stent (SE) stent
- DES balloon-expandable stent (BE) Zotarolimus-eluting (Medtronic Resolute)

The antiplatelet therapy in both cohorts will consist of at least 100 mg of aspirin indefinitely. All patients receive clopidogrel or prasugrel 75 mg of 5-10mg daily for at least 12 months post-stent implantation.

Study burden and risks

risks under the risks of percutaneous treatment of acute myocardial infarction.
The load consists of a re-catheterisation (+standard risks as described in the brochure of the Dutch Heart Foundation)
A clinic visit
4 phone consultations

Contacts

Public
Stentys

Rue Choiseul 25
Parijs 75002
FR
Scientific
Stentys

Rue Choiseul 25
Parijs 75002
FR

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

clinical:
1. Aged between 18 and 80 years.
2. Patients with ST-elevation myocardial infarction in the ambulance or in the cathlab >= 0.2 mV of ST-segment elevation in at least two consecutive leads, <12 hours after the onset of symptoms for >= 20 min
3. Target lesion is a de novo lesion
4. Signed authorization for informed patients
Angiography:
5. Diameter of the vessel is between 2.5 and 4.0mm corresponding to the available STENTYS and Resolute stent sizes (by visual assessment).
6. Target lesion <= 25mm in length (visual assessment).

Exclusion criteria

clinical:
1. Pregnant women or nursing woman or woman of childbearing age without adequate contraception
2. Participation in another clinical study that the primary endpoint has not yet reached, or which interferes with the current study endpoints.
3. Coronary intervention or cardiac or major surgery <30 days ago.
4. Target vessel is a blood vessel that has a bypass.
5. Patient using Coumadin
6. Known hypersensitivity to aspirin, clopidogrel, heparin, stainless steel, sirolimus, Zotarolimus, contrast material.
7. Known thrombocytopenia (PLT <100,000 / mm3).
8. Active bleeding or coagulopathy or chronic anticoagulant therapy
9. Cardiogenic shock
10. Elective surgery and that discontinuation of dual antiplatelet therapy (DAPT) therapy is required.
11. Significant comorbidity which have the probability of non-compliance to clinical follow-up or affect the scientific integrity of the research (as judged by the investigator).
12. Left ventricular ejection fraction (LVEF) <30%.
13. Stroke or TIA within the last 6 months.;Angiography:
14. Severely tortuous, calcified or angulated coronary anatomy of the target vessel that in the opinion of the investigator would result in suboptimal imaging or excessive risk of complications from the placement of an OCT catheter.
15. Myocardial infarction due to stent thrombosis or infarction lesion in a previously stented coronary artery.
16. Unprotected left main stenosis> 30% (visual assessment)
17. Patients with significant lesions in two coronary arteries that require additional treatment within 30 days.
18. Patients with significant lesions in all three coronary arteries

19. Target lesion is a chronic total occlusion
20. Perforated drum, demonstrated by leakage of contrast.
21. Aneurysmal dilation, proximal or distal to the lesion

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-08-2012
Enrollment:	75
Type:	Actual

Medical products/devices used

Generic name:	self-expandable stent
Registration:	No

Ethics review

Approved WMO Date:	11-07-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-11-2012

Application type:	Amendment
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	NL39177.078.12