TRI-stent Adjudication Study - Low risk of Restenosis

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27491

Source
NTR

Brief title
TRIAS-LR

Health condition

elective PCI, low risk of restenosis, endothelial progenitor cells, bare metal stent

Sponsors and support

Primary sponsor: Investigator initiated study, AMC-UvA
Source(s) of monetary or material Support: AMC-UvA

Intervention

Outcome measures

Primary outcome

The primary endpoint is target lesion failure within one year, defined as the composite of cardiac death, myocardial infarction (unless documented to arise from a non-treated coronary artery) and clinically driven repeat revascularization of the treated target lesion.

Secondary outcome

The secondary endpoints are:
1. Procedural success, defined as a less than 20% residual stenosis by off-line QCA and TIMI 3 flow post PCI procedure of the treated vessel;
2. Target lesion revascularization within two, three, four, or five years;
3. Target lesion failure within two, three, four, or five years;
4. Target vessel revascularization within one, two, three, four, or five years;
5. Target vessel failure within one, two, three, four, or five years;
6. In-stent late loss within one year;
7. In-segment late loss within one year;
8. Stent thrombosis within one, two, three, four, or five years;
9. Hospitalization for acute coronary syndrome within one, two, three, four, or five years ;
10. Cardiac death or myocardial infarction within two, three, four, or five years

Study description

Background summary

Objectives
The primary objective of this study is to show superiority of the Genous EPC capturing stent compared to a bare metal stent in its capacity to prevent target lesion failure within one year in statin treated patients undergoing a percutaneous intervention of a de novo, coronary artery lesion(s) with a low risk of restenosis.
The secondary objective of this study is show non-inferiority of the Genous EPC capturing stent relative to a bare metal stent with regard to the long-term incidence of (potentially stent thrombosis related) cardiac death or myocardial infarction.
Patient selection
In this European, multi-center, prospective, randomized trial a total of 1260 clinically stable patients with coronary artery lesions with a low risk of restenosis and an indication for elective percutaneous coronary treatment are randomized. A target lesion is considered to be at low risk of restenosis if all of the following apply: (1) A de novo lesion located in a native epicardial vessel with a Reference Vessel Diameter (RVD) greater than 2.8 mm by visual estimation, (2) a de novo lesion with a length of smaller than 20 mm by visual estimation, (3) a de novo lesion with a TIMI flow equal to or greater than 1, (4) the patient does not have diabetes mellitus.
Suitable candidates are either patients with stable exercise-induced angina or patients stabilized after an episode of unstable angina or non-ST elevation myocardial infarction. Furthermore, all patients entered into this trial have lesions suitable for treatment with either study stent. Patients must have been on statin therapy for at least seven days. Patients with coronary artery lesions considered at high risk for restenosis are excluded from this trial.
Randomization and treatment
All included patients are randomly assigned in a 1:1 ratio to the Genous EPC capturing stent or a bare metal stent.
Patients with multiple lesions are eligible if all target lesions are low-risk lesions. The randomized treatment assignment must be followed for all treated lesions. Clopidogrel is

started before or during PCI procedure and continued on a daily basis for a minimum of four weeks, irrespectively of the type of stent used. The prescribed statin should be atorvastatin in a dosage of at least 40 mg or other statins in equivalent dosages and should be continued for the duration of the study.
Follow-up
Patients are followed clinically by telephone contact at 30 days, six months, one year, two, three, four and five years following the index stenting procedure.
Scheduling of angiographic evaluation of the treated lesion(s) is at the discretion of the treating physician. Repeat coronary angiography, if performed, is preferably scheduled after twelve months and angiograms should be suitable for off-line quantitative coronary angiography.
Endpoints
The primary efficacy endpoint is target lesion failure within one year, defined as the composite of cardiac death, myocardial infarction (unless documented to unequivocally arise from a non-treated coronary artery) and clinically driven repeat revascularization of any of the treated target lesions.
The main long-term endpoint is defined as cardiac death or myocardial infarction (unless documented to unequivocally arise from a non-treated coronary artery) within five years.
The secondary endpoints are: (1) procedural success, defined as a less than 20% residual stenosis by off-line QCA and TIMI 3 flow post PCI procedure of the treated vessel, (2) target lesion revascularization, (3) target lesion failure, (4) target vessel revascularization, (5) target vessel failure, (6) in-stent late loss, (7) in-segment late loss, (8) stent thrombosis, (9) hospitalization for acute coronary syndrome, (10) cardiac death or myocardial infarction.

Study objective

In this multi-center, prospective, randomized trial a total of 1260 patients with lesions with a low risk of coronary restenosis and an indication for percutaneous coronary treatment are randomized to evaluate the superiority of the Genous™ EPC capturing stent as compared to a bare metal stent

Intervention

Elective PCI with stent placement

Contacts

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Eligibility criteria

Inclusion criteria

Clinically stable patients undergoing a PCI for a coronary artery lesion with a low risk of restenosis are candidates for entry into this study.
A target lesion is considered to be at a low risk of restenosis if all of the following apply:
1. A de novo lesion located in a native epicardial vessel with a Reference Vessel Diameter (RVD) greater than 2.8 mm by visual estimation;
2. A de novo lesion with a length of smaller than 20 mm by visual estimation;
3. A de novo lesion with a TIMI flow equal to or greater than 1;
4. The patient does not have diabetes mellitus

Exclusion criteria

1. Younger than 18 years of age;
2. A target lesion located in the left main coronary artery;
3. A chronic, totally occluded (CTO) target lesion;
4. A target lesion with involvement of a side branch, which is equal to or greater than 2.0 mm in diameter by visual estimation;
5. A restenotic target lesion;
6. A target lesion in an arterial or saphenous vein graft or distal to a diseased arterial or saphenous vein graft;
7. A target lesion(s) with an indication for treatment with a drug-eluting stent (DES).
8. Urgent need for revascularization;
9. ST Elevation Myocardial Infarction (STEMI) within the past six weeks;
10. Ventricular tachyarrhythmias within the past week;
11. A diabetic patient ;
12. Known renal insufficiency (e.g. serum creatinin level of more than 200 ìgram/L);
13. Platelet count of less than 100,000 cells/ mm3 or more than 700,000 cells/ mm3, a WBC of less than 3,000 cells/ mm3, or documented or suspected liver disease (including laboratory evidence of hepatitis);

14. History of a bleeding diathesis, or evidence of active abnormal bleeding within 30 days of randomization;
15. History of a hemorrhagic stroke at any time, or stroke or transient ischemic accident (TIA) of any etiology within 30 days of randomization;
16. Previous or scheduled chemotherapy or radiotherapy within 30 days prior or after the procedure;
17. On immune-suppression therapy or with known immunosuppressive or autoimmune disease (e.g. human immunodeficiency virus, systemic lupus erythematosus etc.)
18. Severe hypertension (systolic blood pressure > 180 mmHg or diastolic blood pressure over 100 mmHg, after treatment)
19. Contraindication for treatment with the Genous™ EPC capturing stent, such as previous administration of murine therapeutic antibodies and exhibition of sensitization through the production of Human Anti-Murine Antibodies (HAMA).
20. Known hypersensitivity or contraindication to aspirin, heparin or clopidogrel;
21. Elective surgery, planned within the first 6 months after the procedure that requires discontinuing either aspirin or clopidogrel;
22. Previous heart transplant or any other organ transplant;
23. Previous participation in this study;
24. Circumstances that prevent follow-up (no permanent home or address, transient, etc.);
25. Women who are pregnant or who are of childbearing potential who do not use adequate contraception.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	1260
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-06-2007
Application type:	First submission

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
NTR-new	NL972
NTR-old	NTR999
Other	:
ISRCTN	ISRCTN47701105

Study results