

TRI-stent Adjudication Study - High risk of Restenosis

Submission date 16/07/2007	Recruitment status No longer recruiting	☐ Prospectively registered ☒ Protocol
Registration date 16/07/2007	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 03/01/2012	Condition category Circulatory System	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NTR998

Study information

Scientific Title

Acronym
TRIAS-HR**Study objectives**

In this multicentre, prospective, randomised trial a total of 1300 patients with coronary artery lesions with a high risk of restenosis and an indication for percutaneous coronary treatment are randomised to evaluate the non-inferiority of the Genous™ Endothelial Progenitor Cell (EPC) capturing stent as compared to the Taxus® Paclitaxel Eluting Stent (PES) or Cypher® Sirolimus Eluting Stent (SES). The Genous™ EPC capturing stent is coated with an antibody that captures circulating EPCs for accelerated natural healing.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Academic Medical Centre Medical Ethics Committee on the 12th March 2007 (ref: MEC 07/041 # 07.17.0400).

Primary study design

Interventional

Study design

Multicentre prospective randomised controlled parallel group trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Coronary artery lesions with a high risk of restenosis and an indication for percutaneous coronary treatment

Interventions

All included patients are randomly assigned in a 1:1 ratio to the Genous™ EPC capturing stent or a drug eluting stent. Multiple stent placement is allowed. The randomised treatment assignment must be followed for all high-risk target lesions and for low-risk target lesions located in the same vessel as a high-risk target lesion. Low-risk target lesions in non-target vessels, if present, may be treated with a bare metal stent or the randomly assigned active stent at the discretion of the investigator.

Clopidogrel is started before or during PCI procedure and continued on a daily basis for a minimum of one month in case of Genous™ EPC capturing stent placement, for at least six months in case of Taxus® PES placement, and for at least three months in case of Cypher® SES placement. 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.

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.

Added 01/02/10:

Enrollment for this trial finished on the 19 of February 2009

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

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 revascularisation of the treated target lesion.

Key secondary outcome(s)

1. Procedural success, defined as a less than 20% residual stenosis by off-line Quantitative Coronary Angiography (QCA) and Thrombolysis in Myocardial Infarction (TIMI) three-flow post PCI procedure of the treated vessel
2. Target lesion revascularisation within one, two, three, four, or five years
3. Target lesion failure within two, three, four, or five years
4. Target vessel revascularisation 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. Hospitalisation for acute coronary syndrome within one, two, three, four, and five years
10. Cardiac death or myocardial infarction within one, two, three, four, or five years

Completion date

01/03/2013

Eligibility

Key inclusion criteria

Clinically stable patients undergoing a Percutaneous Coronary Intervention (PCI) for a native, de novo, coronary artery lesion(s), are candidates for entry into this study.

A target lesion is considered to be at a high risk of restenosis if one or more of the following apply:

1. A chronic total occlusion
2. A lesion with a length equal to or greater than 20 mm
3. A lesion in a coronary artery vessel with a diameter equal to or smaller than 2.8 mm (by visual estimation)
4. Any lesion in a patient with diabetes mellitus (independent of lesion length or vessel diameter)

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

1. Younger than 18 years of age
2. Any target lesion located in the left main coronary artery
3. Any target lesion with involvement of a side branch, which is equal to or greater than 2.0 mm in diameter by visual estimation
4. Any restenotic target lesion
5. Any target lesion in an arterial or saphenous vein graft or distal to a diseased arterial or saphenous vein graft
6. Urgent need for revascularisation
7. ST Elevation Myocardial Infarction (STEMI) within the past six weeks
8. Ventricular tachyarrhythmias within the past week
9. Known renal insufficiency (e.g. serum creatinine level of more than 200 µgram/L)
10. Platelet count of less than 100,000 cells/mm³ or more than 700,000 cells/mm³, a White Blood Cell (WBC) count of less than 3,000 cells/mm³, or documented or suspected liver disease (including laboratory evidence of hepatitis)
11. History of a bleeding diathesis, or evidence of active abnormal bleeding within 30 days of randomisation
12. History of a haemorrhagic stroke at any time, or stroke or Transient Ischaemic Accident (TIA) of any aetiology within 30 days of randomisation
13. Previous or scheduled chemotherapy or radiotherapy within 30 days prior or after the procedure
14. On immune-suppression therapy or with known immunosuppressive or autoimmune disease (e.g., human immunodeficiency virus, systemic lupus erythematosus etc.)
15. Severe hypertension (systolic blood pressure greater than 180 mmHg or diastolic blood pressure over 100 mmHg, after treatment)
16. Contraindication for treatment with the Genous™ EPC capturing stent, such as previous administration of murine therapeutic antibodies and exhibition of sensitisation through the production of Human Anti-Murine Antibodies (HAMA)
17. Contraindication(s) for treatment with the PES or SES
18. Known hypersensitivity or contraindication to aspirin, heparin or clopidogrel
19. Elective surgery, planned within the first six months after the procedure that requires discontinuing either aspirin or clopidogrel
20. Previous heart transplant or any other organ transplant
21. Previous participation in this study
22. Circumstances that prevent follow-up (no permanent home or address, transient, etc.)
23. Women who are pregnant or who are of childbearing potential who do not use adequate contraception

Date of first enrolment

01/03/2007

Date of final enrolment

01/03/2013

Locations

Countries of recruitment

Netherlands

Study participating centre

Academic Medical Centre Amsterdam

Amsterdam

Netherlands

1105 AZ

Sponsor information

Organisation

Academic Medical Centre (AMC) (Netherlands)

ROR

<https://ror.org/03t4gr691>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Academic Medical Centre (AMC) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2010		Yes	No
Results article	results	01/08/2011		Yes	No
	protocol				

Protocol article		01/10/2009		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes