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TRI-stent Adjudication Study - High risk of Restenosis

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.triasrandomization.org

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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).

Study design
Multicentre prospective randomised controlled parallel group trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
01/03/2007

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

Age group
Adult

Sex
Not Specified

Target number of participants
1300

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/mm^3 or more than 700,000 cells/mm^3, a White Blood Cell (WBC) count of less than 3,000 cells/mm^3, 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
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Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

Website

http://www.amc.uva.nl#http://www.amc.uva.nl/

ROR
https://ror.org/03t4gr691

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Academic Medical Centre (AMC) (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	01/10/2009		Yes	No
Results article	results	01/05/2010		Yes	No
Results article	results	01/08/2011		Yes	No