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TRI-stent Adjudication Study - Low risk of Restenosis

Submission date 23/08/2007	**Recruitment status** Stopped	[_] Prospectively registered [X] Protocol
Registration date 23/08/2007	**Overall study status** Stopped	[_] Statistical analysis plan [_] Results
Last Edited 21/03/2014	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims

This study focuses on patients diagnosed with narrowing of the blood vessels that supply the heart muscle with blood. Patients will be treated with a procedure called Percutaneous Coronary Intervention (PCI), in which a small balloon will be inserted via an artery to the area of narrowing and then inflated. Once the blood vessel is enlarged, a small metal tube (a stent) will be placed into the blood vessel to keep it open and the balloon will be removed. The stent will remain in the blood vessel to hold it open so that the blood supply to the heart muscle will increase, which may improve symptoms such as angina.

Several types of stents are available, usually either bare metal or covered with a drug, called drug eluting. A bare metal stent may be susceptible to renarrowing of the surrounding blood vessel due to excess growth of natural tissue. Therefore, a newer type of stent has been developed which is coated with an antibody that attracts your own healing cells, which may improve healing and prevent excessive regrowth of natural tissue in the stent. This stent is called the Genous™ stent and has been approved for use for the treatment of narrowed coronary arteries.

The aim of this study is to investigate the use of the Genous™ stent compared to the standard metal stent and to see whether the two stents produce similar clinical outcomes.

Who can participate?

Clinically stable patients undergoing a PCI for narrowed coronary arteries with a low risk of restenosis (recurrence) from various hospitals in Europe and elsewhere in the world.

What does the study involve?

Patients will be randomly allocated to be implanted with either the Genous™ or the bare metal stent. Patients will not be informed about which type of stent they will receive. The placement of either stent will be carried out by a interventional cardiologist according to the same standard procedure. After the stent has been implanted all participants will be approached for an evaluation over the telephone after one month, six months and one, two, three, four and five years. Patients will be questioned about any possible new heart complaints or other medical concerns that they have experienced.

What are the possible benefits and risks of participating?
Participation in the study is voluntary. If you do not participate in this study, the cardiologist will choose which stent to implant. Every participants is free to withdraw the consent for participation in the study at any time without care or treatment being affected. The study does not involve any extra costs and participants will not receive any financial compensation for taking part in this study.
The usual clinical procedural risks of the implantation process will be explained before the procedure. There is no additional clinical risk associated with this study. This study will help tell us which of the stents best prevents narrowing and reduces long-term complications of this procedure. There are no known risks involved in the allocation of either type of stent. These stents are all approved for routine use. This will not have any effect on the rest of the medical treatment. Taking part in this study will not lead to any further tests.

Where is the study run from?
Academic Medical Centre (AMC) (Netherlands).

When is the study starting and how long is it expected to run for?
The study started in 2006 and is expected to end in 2019.

Who is funding the study?
Academic Medical Centre (AMC) (Netherlands) .

Who is the main contact?
Prof. Dr R.J. de Winter
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Study website
http://www.triasrandomization.org

Contact information

Type(s)
Scientific

Contact name
Dr TRIAS Investigators

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NTR999

Study information

Scientific Title

Acronym
TRIAS-LR

Study objectives
In this multi-centre, prospective, randomised trial a total of 1260 patients with lesions with a low risk of coronary restenosis and an indication for percutaneous coronary treatment are randomised to evaluate the superiority of the Genous™ Endothelial Progenitor Cell (EPC) capturing stent as compared to a bare metal stent.

On 09/12/2013 the anticipated end date was changed from 01/03/2013 to 01/02/2019.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Added 09/12/2013:
1. Medical Ethical Research Committee (METC) Academic Medical Centre - University of Amsterdam, METC-Number 2007_049
2. Central Committee on Research Involving Human Subjects, ARB-Number 16663

Study design
Multicentre randomised single-blinded 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 low risk of restenosis undergoing percutaneous coronary treatment

Interventions
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 randomised 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.

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.

Updated 21/03/2014: the trial has been stopped due to low participant recruitment.

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
The secondary endpoints are:
1. Procedural success, defined as a less than 20% residual stenosis by off-line Quantitative Coronary Angiography (QCA) and TIMI 3 flow post PCI procedure of the treated vessel
2. Target lesion revascularisation within 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, or five years
10. Cardiac death or myocardial infarction within two, three, four, or five years

Overall study start date
01/03/2007

Completion date
01/02/2019

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
Clinically stable patients undergoing a Percutaneous Coronary Intervention (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 Thrombolysis in Myocardial Infarction (TIMI) flow equal to or greater than 1
4. The patient does not have diabetes mellitus

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
1260

Key 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 revascularisation
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 creatinine level of more than 200 µgram/L)
13. 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)
14. History of a bleeding diathesis, or evidence of active abnormal bleeding within 30 days of randomisation
15. History of a hemorrhagic stroke at any time, or stroke or Transient Ischaemic Accident (TIA)

of any aetiology within 30 days of randomisation
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 greater than 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 sensitisation 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 six 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

Date of first enrolment
01/03/2007

Date of final enrolment
01/02/2019

Locations

Countries of recruitment
Netherlands

Study participating centre
Academic Medical Centre Amsterdam
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Academic Medical Centre (AMC) (Netherlands)

Sponsor details
Department of Interventional Cardiology
P.O. Box 22660

Amsterdam
Netherlands
1100 DD

Sponsor type
Hospital/treatment centre

Website
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