A safety evaluation of the Genous Bio-engineered R stent in the treatment of patients with ST segment elevation myocardial infarction.

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

Summary

ID

NL-OMON29854

Source
ToetsingOnline

Brief title
HEALING AMI study

Condition

- Coronary artery disorders

Synonym
ST segment elevation myocardial infarction

Research involving
Human

Sponsors and support

Primary sponsor: OrbusNeich Medical CO. LTD

Source(s) of monetary or material Support: OrbusNeich Medical CO LTD.

Intervention

Keyword: Bio-engineered R stent, myocard infarction, safety., ST segment elevation

Outcome measures

Primary outcome

Early stent thrombosis at 30 days post-procedure.

Secondary outcome

· Device, lesion, angiographic and procedure success

· Clinically-driven Target Lesion Revascularization (TLR) and Target Vessel

Revascularization (TVR) at 6 and 12 months

· Major Adverse Cardiac Events (MACE) at 30 days, 6 and 12 months

· Stent thrombosis at 6 months and 12 months (include early and late, probable

and

definite).

· Late stent thrombosis (definite and probable).

· In-stent and in-lesion minimum lumen diameter (MLD), % diameter stenosis

(DS), late

loss and angiographic binary restenosis (> 50% DS) at 6 months post procedure.

Data Coordinating Analysis Center

Study description

Background summary

This is a single center, prospective, non-randomized study. Approximately 50 patients from one center in Europe will be included in this study. Patients

will be
followed clinically at 30 days, 6 months and 12 months following the index procedure with the Genous Bio-engineered R stent. In addition, all patients will be
consented to receive an angiographic follow-up at 6 months post-procedure. All patients will have blood samples drawn for evaluation of endothelial progenitor cells (EPC) count at the time of procedure, 30 days and at 6 months post-procedure.
It is anticipated that the entire duration of this study will be 15 months (3 months to complete enrollment and 12 months follow-up)
All patients will receive a loading dose of atorvastatin (80 mg), aspirin (300 mg) and clopidogrel (300 mg) or ticlopidine (500 mg) if allergic to clopidogrel. Patient will
be treated with one month of clopidogrel (75mg/day) or ticlopidine 250mg/day and aspirin (100mg/day) indefinitely. In addition, patients will be treated with atorvastatin (80mg) for at least 6 months post-procedure. The use of glycoprotein
IIB/IIIA inhibitors will be at the investigator*s discretion.

Study objective

The primary objective of this study is to determine the feasibility and safety of the Genous Bio-engineered R stent in the treatment of patients presenting with acute myocardial infarction with ST segment elevation within 12 hours of symptoms onset, undergoing an invasive primary angioplasty reperfusion strategy.

Study design

Single center, prospective, non-randomized study.

Intervention

Blood samples will be taken at the follow up visits, after 30 days, 6 months and 12 months. A total amount of 50 ml of blood will be taken per visit. A follow up angiographic will be done 6 months after the procedure.

Study burden and risks

Blood samples will be taken at the follow up visits, after 30 days, 6 months and 12 months. A total amount of 50 ml of blood will be taken per visit. A follow up angiographic will be done 6 months after the procedure

Contacts

Public
OrbusNeich Medical CO. LTD

5363 NW 35th Avenue
33309 Fort Lauderdale
USA
Scientific
OrbusNeich Medical CO. LTD

5363 NW 35th Avenue
33309 Fort Lauderdale
USA

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients must meet ALL of the following criteria:
1. Patient >= 18 and <= 80 years of age.
2. ST-segment elevation of >= 1 mm in >= 2 contiguous leads, or (presumably new) left bundle branch block, or true posterior MI with ST depression of >= 1 mm in >= 2 contiguous anterior leads.
3. Treatment of one or two de novo lesions in the same vessel with a total lesion length of <= 30mm. Patients with multi vessel disease not requiring treatment of other lesions within 30 days following treatment of the infarct lesions may be included.
4. Target lesion is located in a native coronary artery.
5. Reference vessel diameter >= 2.5 and <= 3.75 mm by visual estimate.
6. Total lesion length <= 30mm by visual estimate.
7. Acceptable candidate for coronary artery bypass surgery (CABG).

8. The patient has been informed of the nature of the study agrees to its provisions and has provided written informed consent, approved by the appropriate Medical Ethics Committee.
9. Must have clinical symptoms consistent with AMI (e.g., angina or anginal equivalent) lasting <= 30 minutes but < 12 hours in duration. If the symptom duration at the time of evaluation is <1 hour, to rule out unstable angina, the symptoms must be unresponsive to nitroglycerin (i.e. ongoing) prior to signing the informed consent. Patients with symptom onset within 12 hours, in whom the symptoms lasted > 1 hour but subsequently resolved, may still be enrolled if the ECG, at the time of the evaluation, shows definitive ongoing ST segment elevation.

Exclusion criteria

1. Woman who are preganant or woman of childbearing potential who do not use adequate contraception.
2. Recipient of heart transplant.
3. Any patient who previously received murine therapeutic antibodies and is know to have exhibited sensitization through the production of Human Anti-mouse Antibodies (HAMA).
4. Patient with life expectancy less than the follow-up period (12 months).
5. Know allergies to aspirin, clopidogrel bisulphate an ticlopidin, heparin or stainless steel.
6. Patients pesenting with cardiogenic shock.
7. Received thrombolytic therapy for the current STEMI.
8. Lesion is not suitable for stenting.
9. Any significant medical condition which in the investigator's opinion may interfere with the patient's optinonal participation in the study.
10. Currently participatinf in an investigational drug or antother device study or subject to inclusion in another investigational srug or other another device study during follow-up.
11. Unprotected left main coronary disease with >50% stenosis.
12. Ostial target lesions.
13. Calcified lesions which cannot be successfully predilated.
14. Targer lesion has excessive tortuosity unsuitable for stent delivery and deplyment.
15. Target lesion involves bifurcation including a side brach >2.5 mm in diameter (either stenosis of both main vessel and major side branch or stenosis of just major side branch) that would require stenting of diseased side branch).
16. A significant (>50%) stenosis proximal or distal to the target lesion or in another vessel that is not the infarct lesion and requires treatmetn during the acute procedure or within 30 days of enrollment.
17. Documented ejection fraction <25% within 6 weeks of patient enrollmetn on th estudy.
18. pre-treatment with devices other than balloon angioplasty.
19. Prior stent within 10mm target lesion.
20. Patient presenting with possible/probable stent thrombosis.
21 Any patient in whom angiography demonstrates the infarct lesion to be at the site if a previously implanted stent (bare metal or drug-eluting)
22 Patients who underwent coronary stent implamentation within the past 30 days.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-08-2006
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	12-06-2006
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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	NL11812.075.06