Healing IIB Healthy Endothelial Accelerated Lining Inhibits Neointimal Growth

Published: 11-01-2007
Last updated: 20-05-2024

The primary objective of this study is to evaluate the safety and effectiveness of the Genous Bio-engineered R stentTM in conjunction with optimal statin therapy (80mg of atorvastatin), in the treatment of elective patients with up to two de novo...

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

Summary

ID

NL-OMON30049

Source
ToetsingOnline

Brief title
HEALING IIb

Condition

- Coronary artery disorders

Synonym
coronary artery lesions

Research involving
Human

Sponsors and support

Primary sponsor: genae associates
Source(s) of monetary or material Support: Orbus International,Orbus Medical Technologies Inc

Intervention

Keyword: angioplasty, Stent

Outcome measures

Primary outcome

Primary Endpoint

The primary endpoint of this study is in-stent late loss at 6 months by

Quantitative Coronary Angiography (QCA).

Secondary outcome

- Angiographic success

- Procedure success

- Angiographic and/or clinical stent thrombosis

- In-stent late loss at 18 months

- Binary restenosis rate at 6 and 18 months

- In-segment late loss at 6 and 18 months

- Volumetric assessment (derived from QCA parameters) at 6 and 18 months

- Circulating endothelial progenitor cell (EPC) count at screening, index

procedure and at 30 days.

- Target Vessel Failure (TVF) at 30 days, 6, 12, 18 months and at 2, 3, 4 and 5

years

- Major adverse cardiac events (MACE) at 30 days, 6, 12, 18 months and at 2, 3,

4 and 5 years

- Clinically-driven Target Lesion Revascularization (TLR) free rate at 30 days,

6, 12 and 18 months and at 2, 3, 4 and 5 years

- Protocol related serious adverse events (SAEs) up to 5 years

- Change in human anti-murine antibody (HAMA) plasma levels at 1 and 6 months

follow-up as compared to baseline.

Study description

Background summary

By recruiting the patient*s own EPCs to the site of vascular injury (e.g. the site of a coronary stent implant), an acceleration of the normal endothelialization process would occur. It is further theorized that the rapid establishment of a functioning endothelial layer may promote the transformation of the injured site to a healthy state. For example, in the case of coronary stent implantation, rapid re-endothelialization may reduce inflammation, thrombosis and potentially eliminate restenosis.
Patients are asked to take 80 mg of Atorvastatin two weeks prior to the procedure up to six weeks post-procedure to increase the EPC in the blood.

Study objective

The primary objective of this study is to evaluate the safety and effectiveness of the Genous Bio-engineered R stentTM in conjunction with optimal statin therapy (80mg of atorvastatin), in the treatment of elective patients with up to two de novo native coronary artery lesions.

Study design

This is a multi-center, prospective, non-randomized study. Approximately 90 patients from up to 16 centers will be entered in the study.

Patients will be followed clinically for up to 5 years post-procedure. All patients will have a repeat angiography at 6 and 18 months follow-up.

Intervention

Patient will receive a stent implantation according to the hospital practice. After implantation the usual follow up and monitoring wil be performed

Study burden and risks

- The formation of a blood clot that would partially or totally block the blood flow (3-5%)
- Death (1.5%)

- A bleeding that requires surgery (5.6%) or blood transfusion (5.4%)
- Standard medication that you will receive (aspirin and clopidogrel) Aspirin may increase the likelihood of gastrointestinal adverse effects and bleeding. Clopidogrel is uncommonly associated with rash, diarrhea, nausea, vomiting, stomach pain, an increase in cholesterol levels, a drop in the number of white blood cells (which could lead to an increased risk of infection), or a drop in the number of platelets (which could lead to an increased risk of bleeding).
- The use of atorvastatin may increase the likelihood of gastrointestinal adverse effects, muscular pain and impairment of liver function.
- The Genous stent, has a special surface which allows this stent to capture your EPCs. The surface contains a minute quantity of an animal protein. You may have an immune reaction to this surface which may result in allergic type reactions. If this occurs, there is a risk that future treatment with a monoclonal antibody may be compromised.
- Although very unlikely, there may be unforeseeable risks that are not known at this time. There is always the risk that you may require another intervention or coronary by-pass surgery.

Contacts

Public
genae associates

Paleisstraat 24
2018 Antwerpen
Belgie
Scientific
genae associates

Paleisstraat 24
2018 Antwerpen
Belgie

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-Treatment of 1 or 2 de novo lesions;
-Target lesion(s) is(are) located in a native coronary artery, which can be covered by one single stent of maximum 33 mm;
- Reference vessel diameter min.2.5 and max.3.75 mm by visual estimate;
- Target lesion stenosis is >50% and <100%;
- The patient has been informed of the nature of the study agrees to its provisions and has provided written informed consent.

Exclusion criteria

- A Q-wave or non-Q-wave myocardial infarction within 72 hours preceding the index procedure, unless the CK and CK-MB enzymes or Troponin levels are less than twice the Upper Normal Limit;
- Documented or suspected liver disease;
- Recipient of heart transplant;
- Known allergies to aspirin, clopidogrel bisulphate and ticlopidine, heparin, or stainless steel;
- Any patient who previously received murine therapeutic antibodies and exhibited sensitization through the production of Human Anti-mouse Antibodies (HAMA).

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2007
Enrollment:	32
Type:	Actual

Medical products/devices used

Generic name:	Genous bio-engineered R stent
Registration:	Yes - CE intended use
Product type:	Medicine
Brand name:	lipitor
Generic name:	atorvastatine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	11-01-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-01-2007
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2006-006481-42-NL
CCMO	NL13206.078.06