CUSTOM III Trial (Xtent Custom NX 60 Drug Eluting Stent (ES) Catheter System Trial

Published: 22-05-2007
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Primary objective: To gather safety data regarding the clinical performance of the Xtent device in patients treated for coronary artery disease.

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

Summary

ID

NL-OMON30652

Source
ToetsingOnline

Brief title
CUSTOM III Trial

Condition

- Coronary artery disorders

Synonym
atherosclerose, coronary artery sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Xtent Inc.
Source(s) of monetary or material Support: contract met industrie,XTENT

Intervention

Keyword: DES, PCI

Outcome measures

Primary outcome

Primary Endpoint: The rate of Major Adverse Cardiac Event (MACE) at 30 days

(1 month).

Secondary outcome

Secondary Endpoints: Include MACE rate at 6 months, the incidence of bleeding

and/or vascular complications, the incidence of (sub)acute stent thrombosis

(SAT) at discharge, 30 days (1 month) and 6 months. In addition: angiographic

endpoints, device performance endpoints and other safety endpoints.

Study description

Background summary

Study Justification

The XTENT® Custom NX 60 DES Catheter System allows for customized implantation of balloon expandable stents. This catheter system enables the physician to adjust the stent length to the length of lesion to be treated within the coronary vasculature. This assessment in situ is taking place in the same setting as the stent implantation and it does not require the physician to decide in advance the stent length to be implanted. Additionally, the XTENT® Custom NX 60 DES Catheter system allows for the deployment of up to two drug eluting stents per catheter. The drug eluting stents used in the Custom NX 60 DES Catheter System utilize the proven Biolimus A9 and PLA coating formulation.

While the patient risks associated with the XTENT® Custom NX 60 DES Catheter System is similar to current DES stent and delivery systems used for coronary revascularization, the XTENT® DES Catheter Systems should offer advantages to current marketed products such

as:

customization of stent length in situ avoiding estimation of stent length from fluoroscopy and possible in situ placement of suboptimal stent length, treatment of single long lesions (up to 60 mm), longer than all currently available DES stents,
Ability to treat more than one lesion with one catheter reducing catheter exchange and therefore the length of the procedure and possibly the patient exposure to radiation or additional contrast injection.

Study objective

Primary objective: To gather safety data regarding the clinical performance of the Xtent device in patients treated for coronary artery disease.

Study design

This study is a prospective registry enrolling a target up to 110 (Ninety (90) patients plus up to 20 roll-in) subjects at 15 European clinical sites.

Intervention

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Study burden and risks

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Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- at least 18 years
- acceptable candidate for PTCA
- clinical evidence of ischemic heart disease
- target lesion are de novo and stenosis >50% and <100%
- reference vessel diameters >2,25 mm and < 3,75 mm.

Exclusion criteria

- left ventricular ejection fraction <30%
- history of cerebrovascular accident (CVA) or transitory ischemic attack (TIA) in prior 3 months
- evidence of an acute myocaridal infarction whose onset began within 72 hours ago

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-06-2007
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO

Date:	22-05-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL15019.041.06