A Prospective, Multicenter, European Registry Investigating the Lutonix Paclitaxel-Coated Balloon for the Treatment of In-Stent Restenosis within Bare-Metal Stents

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To assess angiographic and clinical outcomes after treatment of ISR of a prior BMS in the native coronary system with the Lutonix Catheter

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

Summary

ID

NL-OMON33458

Source
ToetsingOnline

Brief title
PERVIDEO I Registry

Condition

- Coronary artery disorders

Synonym
restenotic lesions - stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Lutonix
Source(s) of monetary or material Support: Sponsor van het onderzoek

Intervention

Keyword: In-Stent Restenosis, Paclitaxel-Coated Balloon

Outcome measures

Primary outcome

Percent (%) Diameter Stenosis (DS) in the Analysis Segment at 6 months

Secondary outcome

Clinical (at 1, 6, 12 & 24 months)

- Ischemia-driven target vessel revascularization (ID-TVR) defined as targe vessel diameter of at least 50% by Quantitative Coronary Analysis (QCA) with either ECG changes at rest or a positive functional study in the distribution of the target vessel, or stenosis of at least 70% irrespective of symptoms.
- Ischemia-driven target lesion revascularization (ID-TLR)
- Composite of cardiac death, myocardial infarction, and ID-TLR
- Composite of cardiac death, myocardial infarction and target vessel revascularization TVR
- Procedural success
- Device success

Study description

Background summary

The study will enroll approximately 40 patients presenting with angiograpically significant in-stent restenosis (ISR) of a previously placed bare-metal stent (BMS). patients will be treated with the Lutonix Catheter. Clinical follow-up will occur at 1, 6, 12 and 24 months. Repeat angiography/Intravascular Ultrasound (IVUS) will occur at the 6 month clinical visit.

Study objective

To assess angiographic and clinical outcomes after treatment of ISR of a prior BMS in the native coronary system with the Lutonix Catheter

Study design

A Prospective, Single-Arm, Multicenter, European Registry

Intervention

The intervention is the same as usual performed by patients with in-stent restenosis with exception of the IVUS. IVUS is not part of the standard procedure but is performed on regular basis during an PCI/

Study burden and risks

The risks of the PCI are the same as a regular PCI.
The repeat angiography is an extra procedure and therefore an extra risk. Those risks are the same as for an regular diagnostic angiography

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

Target lesions is in a native coronary with previous single bare metal stent
Stenosis is >50% and <100% by visual estimate or QCA prior to defined pre-dilatation

Exclusion criteria

History of MI or thrombolysis within 72 hours of randomization
History of previous target vessel perforation
Angiographic evidence of thrombus or dissection within the target vessel

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-07-2009
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Lutonix Paclitaxel-Coated Balloon
Registration:	No

Ethics review

Approved WMO Date:	02-07-2009
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL27997.060.09