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An international, multicentre prospective single arm study to investigate procedural, clinical and angiographic outcomes using the Taxus Liberte stent, with improved side branch access, following the provisional side branch T-stenting approach, in patients with complex lesions

Submission date
08/02/2007

Recruitment status
No longer recruiting

Registration date
08/02/2007

Overall study status
Completed

Last Edited
08/02/2007

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
LIBERTY ONE

Study objectives
The purpose of the LibertÉ One study is to assess procedural, clinical and angiographic outcomes of the provisional T-stenting approach with the Taxus Liberte stent implanted in complex lesions (with side branch involvement). The Taxus Liberte stent has larger cell perimeters and as such an improved side branch access.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
International, multicentre prospective single arm study

Primary study design
Interventional

Secondary study design
Multi-centre

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Coronary lesions

Interventions
Percutaneous Coronary Intervention (PCI), provisional side branch T-stenting.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Target lesion revascularisation of the main branch and side branch defined by the independent core lab at nine months follow-up.

Secondary outcome measures
1. Incidence of Major Adverse Cardiac Events (MACE) defined as all cardiac deaths, Q-wave and non-Q wave myocardial infarction, target lesion revascularisation (defined as both the main and the side branch) including Percutaneous Transluminal Coronary Angioplasty (PTCA) and Coronary-Artery Bypass Grafting (CABG) at one, seven, nine and 12 months follow-up
2. Acute success rate of stent delivery, recross, and final kissing balloon dilatation, and the number of a second stent implanted on the side branch
3. Restenosis will be evaluated by compulsory nine months angiogram using the binary definition (greater than 50% in diameter) in the main and the side branch vessel. Measure of the absolute lumen diameter will occur before, immediately after and at nine months, reflecting the net gain, difference of acute gain and late loss ratio and late loss index. Additional usual and lesion specific (main and side branch) quantitative results will be analysed
4. Target lesion and target vessel revascularisation of the main and side branch separately at seven, nine and 12 months follow-up

Overall study start date
01/02/2007

Completion date
31/08/2008

Eligibility

Key inclusion criteria
1. Patients with stable angina pectoris (CCSC1234) or unstable angina and documented ischaemia or silent ischaemia
2. Patient eligible for coronary revascularisation
3. The target lesion has a major native coronary artery (more than 2.5 mm) with a stenosis more than 50% (on visual assessment) located at a side branch (more than 2 mm)
4. A de novo lesion
5. All angle severities (between branches) accepted
6. The main vessel lesion can be covered by one stent (up to 32 mm)
7. Other lesions in different vessels are successfully treated before the treatment of the target lesion (residual stenosis less than 30%, stent well deployed, no residual dissection, normal Thrombolysis in Myocardial Infarction [TIMI] flow, no chest pain, ElectroCardioGram [ECG] unchanged compared to pre-procedural ECG)
8. Only one target lesion can be included in the study
9. Signed patients informed consent

Participant type(s)
Patient

Age group

Not Specified

Sex
Not Specified

Target number of participants
400

Key exclusion criteria
1. Patients with in stent restenosis of target lesion
2. Severe calcifications with an undilatable lesion during balloon predilatation (Percutaneous Transluminal Renal Angioplasty [PTRA] could be considered)
3. History of bleeding diathesis
4. Untreated significant lesion greater than 50% diameter stenosis remaining proximal or distal to the target intervention
5. Patient has suffered a stroke or Transient Ischaemic Attack (TIA) within the past six months
6. Known untreatable malignancy
7. Any major surgery planned or required during the next nine months
8. Acute myocardial infarction
9. Allergy to contrast and/or required antiplatelet medication
10. Left main coronary artery

Date of first enrolment
01/02/2007

Date of final enrolment
31/08/2008

Locations

Countries of recruitment
Netherlands

Study participating centre
Boston Scientific
Maastricht
Netherlands
6201 BJ

Sponsor information

Organisation
New Nantes Private Clinics (Nouvelles Cliniques Nantaises) (France)

Sponsor details

Unit of Care and Interventional Cardiology (UnitÉ de soins et de cardiologie interventionnelle)
4, rue Eric Tabarly
Nantes
France
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Sponsor type
Hospital/treatment centre

Website
http://www.ncn.fr/

ROR
https://ror.org/03731ze76

Funder(s)

Funder type
Industry

Funder Name
Boston Scientific (The 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