

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/02/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/02/2007	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

ROR

<https://ror.org/03731ze76>

Funder(s)

Funder type

Industry

Funder Name

Boston Scientific (The Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration