# An international, multicenter 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.

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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...

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON21479

**Bron**
Nationaal Trial Register

**Verkorte titel**
LIBERTY ONE

**Aandoening**

complex coronary lesions (involving side branches)

## Ondersteuning

**Primaire sponsor:** Dr. Phillipe Brunel
**Overige ondersteuning:** BSCI gives an unrestricted fund and logistic help to perform the study. For logistic reason BSCI pays the investigators per country.

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Target Lesion Revascularization of the Main Branch and Side Branch defined by the independent core lab at 9 months follow-up.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Stented coronary arteries are prone to renarrowing. This may occur in up to 40% of cases at a complex lesions (with side branch involvement). Various techniques are used in treating coronary bifurcation narrowings, inflating balloons, T-stenting,V-stenting,Y-stenting, crush and culotte. These techniques use either one, two or even three stents. The simplest approach is provisional T-stenting. None of these treatments have shown significate superiority.Provisional T-stenting has reported good results with bare metal stents, and is considered to be the "gold standard" technique with this technology. The TAXUS stent is a drug-eluting stent, and this study will establish whether it can be used safely and efficaciously at complex lesions (with side branch involvement), using the stepwise provisional T-stenting techniqe.

### Doel van het onderzoek

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.

### Onderzoeksproduct en/of interventie

PCI, provisional side branch T-stenting

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with stable angina pectoris (CCSC1234) or unstable angina and documented ischemia or silent ischemia;
2. Patient eligible for coronary revascularisation;
3. The target lesion has a major native coronary artery (>2.5mm) with a stenosis > 50% (on visual assessment) located at a side branch (>2mm);
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 32mm);
7. Other lesions in different vessels are successfully treated before the treatment of the target lesion (residual stenosis <30%, stent well deployed, no residual dissection, normal TIMI flow, no chest pain, ECG unchanged compared to pre-procedural ECG;
8. Only one target lesion can be included in the study;
9. Signed patients informed consent.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with in stent restenosis of target lesion;
2. Severe calcifications with an undilatable lesion during balloon predilatation (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 TIA within the past 6 months;
6. Known untreatable malignancy;
7. Any major surgery planned or required during the next 9 months;
8. Acute Myocardial Infarction;
9. Allergy to contrast and/or required antiplatelet medication;
10. Left Main coronary artery.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Anders |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-02-2007 |
| Aantal proefpersonen: | 400 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL869 |
| NTR-old | NTR883 |
| Ander register | : N/A |
| ISRCTN | ISRCTN82823121 |

# Resultaten