

# Sirolimus-coated balloon versus drug-eluting stent in native coronary vessels

Gepubliceerd: 04-08-2021 Laatste bijgewerkt: 18-08-2022

The hypothesis of the TRANSFORM II study is the non-inferiority of Sirolimus Coated Balloon versus Everolimus Eluting Stent in terms of Target Lesion Failure

<b>Ethische beoordeling</b>	Niet van toepassing
<b>Status</b>	Werving nog niet gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON22515

### Bron

Nationaal Trial Register

### Verkorte titel

TRANSFORM II

### Aandoening

Coronary artery disease

## Ondersteuning

**Primaire sponsor:** Fondazione Ricerca e Innovazione Cardiovascolare ETS

**Overige ondersteuning:** Fondazione Ricerca e Innovazione Cardiovascolare ETS

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

To verify the non-inferiority of Magic Touch SCB hypothesized in target lesion failure (TLF), a composite of cardiac death, ischemia-driven target lesion revascularization (TLR), target vessel myocardial infarction (MI), at 12 months

# Toelichting onderzoek

## Achtergrond van het onderzoek

Treatment of lesions allocated in small or mid-sized coronary vessels still represents a challenge for interventional cardiologists and remains an independent predictor for angiographic restenosis, even after the introduction of drug-eluting stents (DES). Several studies have demonstrated the good clinical outcomes of DES, in this particular setting. However, even the latest generations of DES are still associated with a higher incidence of restenosis, vessel thrombosis and myocardial infarction in this setting; without reaching a plateau of adverse events. Lately drug-coated balloons (DCB) have emerged as an attractive alternative for the treatment of coronary de-novo lesions. In the last years, several new generation DCB have been developed, with the aim of improving the trackability and deliverability of these devices, along with an improvement of drug release, especially in tortuous and small vessels. Until 2016, only paclitaxel-eluting DCB were marketed, due to the specific lipophilic properties of paclitaxel, that render this drug particularly appealing for local delivery.

However, currently available DES all elute sirolimus or analogue drugs (the so called "- limus" class) due to the improved outcome shown when compared to paclitaxel-eluting stents, that were abandoned almost a decade ago due to reduced efficacy and increased thrombotic risk. Despite no specific issues were raised for currently available paclitaxel-eluting DCB used for coronary applications, sirolimus has well recognized antiproliferative properties and a wider therapeutic window. The main issue with this drug delivered locally without prosthesis implantation is related to its intrinsic lower lipophilia (thus, the ability of penetrating into tissues), that could hamper its ability to exert local antirestenotic effects.

In 2016, the first sirolimus-coated DCB obtained the CE mark and was marketed in Europe and Asia (Magic Touch, Concept Medical, FL, USA); this balloon elutes sirolimus, a powerful cell growth-inhibitory drug, characterized by a low lipophilicity. This device has been studied in several lesion settings till date, but not by means of a study adequately powered for clinical endpoints.

## Doel van het onderzoek

The hypothesis of the TRANSFORM II study is the non-inferiority of Sirolimus Coated Balloon versus Everolimus Eluting Stent in terms of Target Lesion Failure

## Onderzoeksopzet

- Visit 1 (phone) at 6 Months: Recording of medications and Adverse Events
- Visit 2 (in person) at 12 Months: Clinical Follow-up
- Visit 3 (phone) at 24 Months: Recording of medications and Adverse Events
- Visit 4 (phone) at 36 Months: Recording of medications and Adverse Events

- Visit 5 (phone) at 48 Months: Recording of medications and Adverse Events
- Visit 6 (phone) at 60 Months: Recording of medications and Adverse Events

## **Onderzoeksproduct en/of interventie**

Percutaneous Coronary Intervention

## **Contactpersonen**

### **Publiek**

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### **Wetenschappelijk**

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## **Deelname eisen**

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

- age >18 years;
- all patients with a clinical indication to PCI (stable coronary artery disease or acute coronary syndromes);
- native coronary artery lesion in a vessel with diameter >2.0 mm and  $\leq 3.0$  mm at visual estimation;
- maximum lesion length: 40 mm.
- informed consent to participate in the study.

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

- patients with known (and untreatable) hypersensitivity or contraindication to aspirin, heparin, clopidogrel, prasugrel, ticagrelor, sirolimus or contrast media, which cannot be adequately pre-medicated;
- patients participating in another clinical study;
- subject is a woman who is pregnant or nursing (pregnancy test, either urine or blood test must be performed within 7 days prior to the index procedure in woman of child-bearing potential, and must not commit to initiating a pregnancy for 12 weeks after implantation, using effective contraception);
- creatinine clearance  $<30$  ml/min;
- left ventricular ejection fraction  $<30\%$ ;
- life expectancy  $<12$  months;
- ST-elevation myocardial infarction in the previous 48 hours;
- visible thrombus at lesion site;
- culprit lesion stenosis  $>99\%$  and/or TIMI flow  $<2$ ;
- target lesion/vessel with any of the following characteristics:
  - concomitant PCI at the same vessel with any device (vessels are considered: left anterior descending, circumflex or right coronary artery);
  - pre-dilatation of the target lesion not performed or not successful (residual stenosis  $>30\%$ );
  - severe calcification of the target vessel, at lesion site but also proximally;
  - highly tortuous vessel which could impair device delivery to the lesion site following Investigator's judgement;
  - previous stent implantation at target vessel (left anterior descending artery; circumflex artery; right coronary artery);
  - bifurcation lesion where side branch treatment is anticipated;
  - left main stem stenosis  $>50\%$ ;
  - target lesion is in left main stem

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

### Deelname

Nederland	
Status:	Werving nog niet gestart

(Verwachte) startdatum: 30-09-2021  
Aantal proefpersonen: 1130  
Type: Verwachte startdatum

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

## 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
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NTR-new	NL9678
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Ander register Medical research Ethics Committees United (MEC-U) : Will follow

## Resultaten