The Real-World Endeavor Resolute versus XIENCE V Drug-Eluting SteNt Study in TwentE

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To investigate whether the clinical outcome is similar after the implantation of the Endeavor Resolute stent versus the XIENCE V stent (non-inferiority test).

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20519

Bron
NTR

Verkorte titel
TWENTE

Aandoening

Coronary atherosclerosis
Percutanous Coronary Intervention
Drug-eluting Stent

Ondersteuning

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Overige ondersteuning: Stichting Hartcentrum Twente

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Main study parameter/endpoint:
• Target vessel failure (TVF) at 12 months (according to ARC definitions)

Components of the primary endpoint in hierarchical order:
o Target vessel related death or cardiac death that cannot be clearly attributed to a vessel other than the target vessel. All deaths are considered cardiac, unless an unequivocal noncardiac cause can be established.
o Target vessel related MI (n,%), that is Q-wave or non-Q-wave myocardial infarction that can be related to the target vessel or cannot be related to another vessel.
o Clinically driven repeated target vessel revascularization by means of CABG or PCI (n,%)

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: The introduction of drug-eluting stents (DES) in the treatment of coronary artery disease has led to significant reduction in morbidity but not in mortality.
Second generation DES were developed in an effort to further decrease morbidity and also to decrease mortality.
In our center, two CE-certified second generation DES (Endeavor Resolute stent and XIENCE V stent) are now used in daily clinical routine. There are no data that indicate an advantage of one of these DES over the other (e.g., for certain indications); therefore, we currently make our choice of DES simply by chance.

Objective: To investigate whether the clinical outcome is similar after the implantation of the Endeavor Resolute stent versus the XIENCE V stent (non-inferiority test).

Study design: Single center prospective randomized single-blinded study.

Study population: Patients who require percutaneous coronary intervention (PCI) for the treatment of coronary stenoses with indication for DES use, according to current guidelines and/or the operators clinical judgement. All clinical syndromes will be included with the exception of ST –elevation myocardial infarction.

Intervention: In patients who will receive a DES anyway, we will randomize the type of DES implanted (Endeavor Resolute stent vs. XIENCE V stent). Both DES are already used in our

routine PCI procedures. At this time, no data are available that may suggest the superiority of one of the above-mentioned DES over the other.

Main study endpoints: The primary endpoint is the incidence of target vessel failure at one year follow-up. Target vessel failure (TVF) is any target vessel revascularization, death, or MI which is attributable to the target vessel or not attributable to another vessel. Further secondary clinical and angiographic endpoints will be investigated and have been defined in accordance with the consensus paper of the Academic Research Consortium (ARC) as published in 2007. Of note, the angiographic assessment is based on clinically indicated projections only and results in no additional x-ray exposure. There is no routine angiographic follow-up. However, if angiographic data are available in patients who undergo symptom-driven re-catheterization, we will analyze these data to get insight into the mechanisms of potential restenosis. In addition, we will analyze clinical intravascular ultrasound (IVUS) images that may be available in a subpopulation of patients (in whom the operator for clinical reasons decides to use IVUS guidance). Of note, there will be no additional IVUS examinations (i.e., no IVUS examination for research purpose only) for this study, but we will analyze the IVUS data from clinical routine where they are available.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Patients will receive the routine treatment provided in our center. As a consequence, the risks of this trial do not exceed the risks of any routine PCI procedure at Medisch Spectrum Twente, because the PCIs in this study will not deviate in any way from the local clinical routine.

Doel van het onderzoek

To investigate whether the clinical outcome is similar after the implantation of the Endeavor Resolute stent versus the XIENCE V stent (non-inferiority test).

Onderzoeksopzet

Baseline, 1 month, 3 months, 1 year, 2 year

Onderzoeksproduct en/of interventie

Intervention will involve randomization of the type of DES (Endeavor Resolute vs XIENCE V) used in study population. Duration of randomization will be two years.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Indication for PCI with DES implantation based on NVVC/ESC guidelines and/or clinical decision of interventional cardiologist

2. Age ≥ 18 years and mentally capable to give an informed consent

3. Signed informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with ST-elevation myocardial infarction (STEMI) or an ST-elevation myocardial infarction equivalent requiring primary PCI or rescue PCI

2. Patients in whom the revascularization procedure is planned to be performed in a staged approach

3. Renal failure requiring haemodialysis

4. Patient is currently participating in an investigational drug or device study that has been not completed

5. In the investigators opinion patient has a co-morbid condition(s) that could limit the patient’s ability to participate in the study, compliance with follow-up requirements or impact the scientific integrity of the study

6. Life expectancy less than 1 year

7. Patients in whom during PCI there is no indication for DES use and/or if the operator chooses not to use a DES based on the clinical situation, the patient will be excluded

8. When the choice of DES is dictated by logistic reasons e.g. the required DES dimensions is provided by one manufacturer only and not by the other.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2008
Aantal proefpersonen:	1380
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-03-2008
Soort:	Eerste indiening

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	NL1211
NTR-old	NTR1256
Ander register	: MST/Twente/001
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A