DUrable Polymer-based STent CHallenge of Promus ElemEnt versus ReSolute Integrity (DUTCH PEERS): Randomized Multicenter Trial in All-Comers Population Treated Within Eastern NeThErlands-2 (TWENTE-2).

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21654

Source
Nationaal Trial Register

Brief title
DUTCH PEERS/ TWENTE-2

Health condition

Percutaneous Coronary Intervention (PCI)
Drug-eluting stent
Coronary atherosclerosis

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Stichting Hartcentrum Twente

Intervention

Outcome measures

Primary outcome

Main study parameter/endpoint:

Target vessel failure (TVF) at 12 months (according to ARC definitions).

Components of the primary endpoint in hierarchical order:

1. Cardiac death. All deaths are considered cardiac, unless an unequivocal non-cardiac cause can be established;

2. Target vessel related MI 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;

3. Clinically driven repeated target vessel revascularization by means of CABG or PCI.

Secondary outcome

Clinical endpoints at 1, 12, 24 month follow-up (with the exception of TVF at 1 year which is the primary endpoint, as described above):

1. Death;

A. Cardiac;

B. Vascular;

C. Other causes;

D. All-cause mortality;

2. Any myocardial infarction;

A. Q-wave;

B. Non Q-wave;

3. Any revascularisation by means of PCI or Coronary Artery Bypass Grafting (CABG);

4. Target vessel related death;

5. Target vessel related myocardial infarction (MI);

A. Q-wave myocardial infarction;

B. Non Q-wave myocardial infarction;

6. Clinically indicated repeated target vessel revascularization (TVR);

A. CABG;

B. PCI;

7. Clinically indicated repeated target lesion revascularization (TLR);

A. CABG;

B. PCI;

8. New onset of angina pectoris:

A. Related to the target vessel;

B. Related to another vessel;

C. Unspecified;

9. Stent thrombosis (Definite, Probable, and Possible; ARC definition):

A. Early;

B. Subacute;

C. Late;

D. Very late;

10. Composite endpoint at one month and 1 and 2 year follow-up (except TVF at one year follow-up which is already the primary endpoint);

11. Target vessel failure (TVF) as defined above;

A. Target Lesion Failure (TLF);

B. Cardiac death;

12. Any myocardial infarction (not clearly attributable to a nontarget vessel;

A. Clinically driven TLR;

13. Major Adverse Cardiac Events (MACE), patient oriented compositie endpoint (hierarchical order);

A. All cause mortality;

B. Any MI (including non-target vessel territory);

C. Any repeat revascularization (target and non-target vessels) by means of CABG or PCI oMACE, device/lesion oriented (hierarchical order);

D. All cause mortality;

E. Any MI (including non-target vessel territory);

F. Emergent coronary-artery bypass surgery, or repeat clinically indicated target-lesion percutaneous or surgical revascularization.

Angiographic endpoints in entire population at final angiographic assessment:

1. At final angiographic assessment the stented segment will be analyzed and the minimum lumen diameter (MLD), reference diameter, percent diameter stenosis (% DS), and mean lumen diameter will be determined. In a subgroup of lesions treated with a single stent and postdilated with balloon pressures within the range of manufacturers' charts, the stented segment will be subdivided into 3 subsegments and in each of them the QCA parameters are determined and the ratio of the MLD to the predicted maximum balloon diameter, as determined from balloon charts provided by the manufacturer, will be calculated as a measure of radial force and potential immediate recoil of the stent. Angiographic endpoints will be assessed in the routine runs recorded during index PCI. The analysis requires no additional angiography runs;
A substudy will include the following angiographic endpoints in subpopulation of patients referred for angiographic re-evaluation and in subpopulation of these patients who will require re-intervention e.g. clinically indicated angiographic re-evaluation.

oIntra-stent Late Lumen Loss (LLL) measured by QCA and defined as the difference between post-procedure minimal lumen diameter (MLD) and the subsequent angiography (segment analysis);

2. MLD, reference diameter, and %DS (percent diameter stenosis; segment analysis);

3. Angiographic evidence of stent thrombosis as outlined in table 6 of the appendix;

4. In subgroups of patients with clinically indicated Intravascular ultrasound (IVUS) and/or Optical Coherence Tomography (OCT) the following will be assessed;

5. In a subgroup of the patients with clinically indicated IVUS or OCT guidance of PCI, image data sets will be analyzed from the runs that may be acquired before PCI, after the stent implantation, and finally at the end of the PCI procedure. These analyses will include measurements of minimal lumen cross-sectional area (CSA) and diameter, mean lumen CSA, adequacy of stent expansion, stent symmetry, adequacy of stent apposition, plaque prolapse, and stent-reference lumen area ratio;

6. In the subgroup of patients with re-PCI for restenosis, the use of IVUS and/or OCT should be considered, which can help to adequately treat patients. In patients with stent thrombosis, the use of IVUS or OCT is strongly recommended, as it may be of critical importance in order to identify the mechanism of stent thrombosis and avoid recurrence of this adverse event. Measurements will include the same as described above in the context of the index procedure with the addition of: measurement of mean neointima, lumen, and stent CSA and volume; in-stent percent volume obstruction; minimum and maximum neointima, lumen, and stent CSA, and minimum and maximum in-stent CSA obstruction; neointima, lumen and stent CSA at the site of the minimum in-stent lumen CSA; and the presence and the extent of late stent malapposition and endothelial strut coverage.

Study description

Background summary

Rationale:

The introduction of drug-eluting stents (DES) in the treatment of coronary artery disease has led to a significant reduction in morbidity but there are further demands on DES performance. Such demands are an optimized performance in very challenging coronary lesions; third generation DES were developed in an effort to further improve DES performance in such challenging lesions. Two CE-certified third generation DES (Resolute Integrity and Promus Element stents) are currently available; there are no data that indicate an advantage of one of these DES over the other.

Objective:

To investigate whether the clinical outcome is similar after implantation of the Promus Element versus the Resolute Integrity stent (non-inferiority hypothesis).

Study design:

Multi-center, prospective, randomized single-blinded study.

Study population:

Patients who require percutaneous coronary interventions (PCI) for the treatment of coronary stenoses with an indication for DES use, according to current guidelines and/or the operators clinical judgement. All clinical syndromes will be included.

Intervention:

In patients who are eligible for DES implantation, the type of DES implanted will be randomized (Resolute Integrity stent versus Promus Element stent). At the start of the study, both DES will also be used in routine clinical practice.

Main study endpoints:

The primary endpoint is the incidence of target vessel failure at one year follow-up. Target vessel failure (TVF) is a composite endpoint consisting of cardiac death, target vessel MI, or clinically driven target vessel revascularization. Further secondary clinical and angiographic endpoints will be investigated, defined in accordance with suggestions of the Academic Research Consortium (ARC). 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. 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 DES restenosis.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Patients will receive the routine clinical treatment. As a consequence, the risks of this trial do not exceed the risks of any routine PCI procedure.

Study objective

To investigate whether the clinical outcome is similar after the implantation of the Resolute Integrity stent versus the Promus Element stent (non-inferiority test).

Study design

Baseline, 1 month, 1 year, 2 years.

Intervention

Intervention will involve randomization of the type of DES (Promus Element versus Resolute Integrity) used in study population. Duration of randomization will be two years.

Contacts

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Eligibility criteria

Inclusion criteria

1. Minimum age of 18 years;

2. Coronary artery disease and lesion(s) eligable for treatment with drug eluting stents according to clinical guidelines and/or the operators' judgement;

3. Patient is willing and able to cooperate with study procedures and required follow-up visits; and patient has been informed and agrees on the participation by signing an EC approved written informed consent.

Exclusion criteria

1. Participation in another randomized drug or device study before reaching primary endpoint;

2. Planned surgery within 6 months of PCI unless dual antiplatelet therapy is maintained throughout the peri-surgical period;

3. Intolerance to a P2Y12 receptor antagonist that results in the patient’s inability to adhere to dual-antiplatelet therapy, or intolerance to aspirin, heparin, or components of the two DES examined;

4. Known pregnancy;

5. Life expectancy of less than 1 year.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2010
Enrollment:	1788
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-07-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2307
NTR-old	NTR2413
Other	METC MST : p10-29
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A