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)

Published: 09-11-2010
Last updated: 04-05-2024

Primary research questions To investigate whether the outcome after the randomized implantation of the Resolute Integrity® versus Promus Element® drug-eluting stent are similar, as assessed in a non-inferiority setting by comparing target-vessel...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON39562

Source
ToetsingOnline

Brief title
DUTCH PEERS (TWENTE-2)

Condition

- Coronary artery disorders
- Cardiac therapeutic procedures
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
arteriosclerose, hardening of the arteries

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Boston Scientific,Medtronic Trading NL BV,Stichting Hartcentrum Twente

Intervention

Keyword: Coronary atherosclerosis, Coronary disease, Drug-eluting stent, Percutaneous coronary intervention

Outcome measures

Primary outcome

* Target vessel failure (TVF) at 12 months

Components of the primary endpoint in hierarchical order:

o Cardiac death. All deaths are considered cardiac, unless an unequivocal

non-cardiac cause can be established.

o 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.

o Clinically driven repeated target vessel revascularization by means of CABG

or PCI

Secondary outcome

* Clinical endpoints at 1,12, 24,36,48,60 month follow-up (with the exception

of TVF at 1 year which is the primary endpoint, as described above):

o Death

o Any myocardial infarction

o Any revascularisation by means of PCI or Coronary Artery Bypass Grafting

(CABG).

o Target vessel related death

o Target vessel related myocardial infarction (MI)

o Clinically indicated repeated target vessel revascularization (TVR)

o Clinically indicated repeated target lesion revascularization (TLR)

o New onset of angina pectoris:

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

* Composite endpoint at one and three month and 12, 24,36,48,60 year follow-up

(except TVF at one year follow-up which is already the primary endpoint) :

o Target vessel failure (TVF) as defined above.

o Target Lesion Failure (TLF)

o Major Adverse Cardiac Events (MACE), patient oriented compositie endpoint

(hierarchical order)

o MACE, device/lesion oriented

* Angiographic endpoints in entire population at final angiographic assessment

:

* A substudy will include angiographic endpoints in subpopulation of patients

referred for angiographic re-evaluation

* In subgroups of patients with clinically indicated Intravascular ultrasound

(IVUS) and/or Optical Coherence Tomography (OCT) endpointswill be assessed

Study description

Background summary

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 lesion. Third generation DES were developed in an effort to further improve DES performance in challenging lesions. Two CE-certified third generation DES (Resolute Integrity and Promus Element stent) are currently available; there are no data that indicate an advantage of one of these DES over the other.

Study objective

Primary research questions

To investigate whether the outcome after the randomized implantation of the Resolute Integrity® versus Promus Element® drug-eluting stent are similar, as assessed in a non-inferiority setting by comparing target-vessel failure (TVF) of both stents at one year follow-up post stent implantation. In brief, we want to compare for both drug-eluting stents the combined endpoint of (1) cardiac death, (2) myocardial infarction that can be related to the target vessel or cannot be related to another vessel, and (3) clinically indicated revascularization related to the target-vessel. Based on the results of the RESOLUTE all-comers trial (the study stents in the RESOLUTE all comers trial used the same coatings and drugs used in the current trial but on different bare metal stent platforms), non-inferiority of Resolute Integrity® and Promus Element® is expected. This is not tested in a controlled randomized trial yet.

Secondary research questions

Effectivity, safety, clinical short- and long-term outcome, and the acute angiographic results of the implantation of two third-generation drug-eluting stents will be compared in a *real world*, all-comers scenario. Angiographic comparison will be based on the routine coronary angiography runs recorded during diagnostic coronary angiography and PCI procedures. No additional mandatory angiographic studies after the index PCI are required.

Study design

Multi-center, prospective, randomized single-blinded study comparing the clinical outcomes of two CE certified 3rd generation drug eluting stent: Resolute Integrity and Promus Element.

Study burden and risks

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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Minimum age of 18 years * Coronary artery disease and lesion(s) eligable for treatment with drug eluting stents according to clinical guidelines and/or the operators* judgement * 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

Participation in another randomized drug or device study before reaching primary endpoint * Planned surgery within 6 months of PCI unless dual antiplatelet therapy is maintained throughout the peri-surgical period * 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 * Known pregnancy * Life expectancy of less than 1 year

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-11-2010
Enrollment:	1788
Type:	Actual

Ethics review

Approved WMO Date:	09-11-2010
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	04-10-2011
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	24-01-2012
Application type:	Amendment

Review commission:	METC Twente (Enschede)
Approved WMO Date:	12-03-2013
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	25-02-2014
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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
Other	Nederlands trial register: NTR2413
CCMO	NL33169.044.10