Comparison of BIOdegradable Polymer and DuRablE Polymer Drug-eluting Stents in an All COmeRs PopulaTion: Randomized Multicenter Trial in an All Comers Population Treated Within thE NeThErlands 3 (TWENTE 3).

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28886

Source
Nationaal Trial Register

Brief title
BIO-RESORT

Health condition

Percutaneous Coronary Intervention (PCI), Coronary atherosclerosis

Sponsors and support

Primary sponsor: Cardio Research Enschede BV
Source(s) of monetary or material Support: Cardio Research Enschede BV

Intervention

Outcome measures

Primary outcome

1. Target vessel failure (TVF) at 12 months (according to ARC definitions) after randomization of Orsiro and Synergy will be compared to Resolute Integrity.

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

Device and patient oriented effectivity and safety parameters such as target-lesion failure, major adverse cardiac events and patient oriented composite endpoint and stent thrombosis, as well as clinical short- and long-term outcome, and the acute angiographic results of the implantation of Orsiro and Synergy will be compared to Resolute Integrity.

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. However, the first generation of these devices had no positive impact on the mortality after PCI (compared to bare metal stents), which was greatly attributed to a somewhat increased incidence of late and very late stent thrombosis. Concerns about the role of durable polymers as a potential trigger of inflammation and finally adverse events also led to the development of DES with biodegradable coatings, which leave after degradation of the coating only a bare metal stent in the vessel wall that does not induce an inflammatory response. While such biodegradable polymer DES are increasingly used in clinical practice, there is no data available from head-to-head comparisons between biodegradable and contemporary third generation durable polymer DES.

Study objective

The aim of the study is to compare the outcome of two DES with biodegradable polymer coatings separately (Orsiro and Synergy) versus an established third-generation durable

polymer DES with proven efficacy and safety (Resolute Integrity) in an all comers patient population and non-inferiority setting.

Study design

Baseline, 1 month, 1 year, 2 years.

Intervention

Intervention will involve randomization of the type of DES (Orsiro or Synergy or Resolute integrity) used in study population.

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Eligibility criteria

Inclusion criteria

1. Minimum age of 18 years;

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

3. Capable of providing informed consent;

4. Patients with all clinical syndromes will be enrolled without any exclusion based on number, type, location, or length of lesions to be treated.

Exclusion criteria

1. Known intolerance to components of one of the stents that will be investigated or known intolerance to antithrombotic and/or anticoagulant therapy that prevents adherence to dual antiplatelet therapy;

2. Planned elective surgical procedure necessitating interruption of dual antiplatelet therapy during the first 6 months after randomization;

3. Participation in another randomized drug or device trial before reaching primary endpoint;

4. Adherence to scheduled follow-up is unlikely or life expectancy assumed to be less than 1 year;

5. Known pregnancy.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2012
Enrollment:	3540
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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	NL3441
NTR-old	NTR3592
Other	METC MST : P12-22
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A