Bioresorbable polymer-coated ORSIRO versus durable polymer-coated RESOLUTE ONYX stents [BIONYX]: A randomized Trial With stENT Evaluation in all-comers IV [TWENTE IV]

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The aim of the study is to compare the outcome of the bioresorbable polymer coated stent (ORSIRO) and a new generation permanent polymer coated stent (RESOLUTE ONYX) in an allcomers patient population and non-inferiority setting.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON47794

Source
ToetsingOnline

Brief title
BIONYX (TWENTE IV)

Condition

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

Synonym
arteriosclerosis, hardening of the arteries

Research involving

Human

Sponsors and support

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

Intervention

Keyword: coronary disease, coronary-atherosclerosis, drug-eluting stent, percutaneous coronary intervention

Outcome measures

Primary outcome

Incidence of target vessel failure (TVF) at 1 year follow-up (according to ARC

definitions). Components of the primary endpoint in hierarchical order:

- Cardiac death: all deaths are considered cardiac, unless an unequivocal

non-cardiac cause can be established.

- Target vessel related myocardial infarction (MI) that is Q-wave or

non-Q-wave, that can be related to the target vessel or cannot be related to

another vessel.

- Clinically driven repeated target vessel revascularization by means of PCI or

CABG.

Secondary outcome

- Target vessel failure (TVF) at 2-year follow-up (TVF at 2-year follow-up is

a Major Secondary Endpoint)

- Death (any / cardiac / non-cardiac)

- Target vessel-related MI (any / periprocedural) and any MI, according to the

current (as of March 2015) ARC definition and addendum (CKmax >2x ULN)

- Clinically-indicated target vessel revascularization (TVR) (any / by PCI / by

CABG)

- Clinically-indicated target lesion revascularization (TLR) (any / by PCI / by CABG)

- Any Revascularization (any / by PCI / by CABG)

- Stent thrombosis (ST) (definite / probable / possible/ definite-or-probable) and time of ST (acute / sub-acute / late / very late) according to the ARC definitions.

- Target lesion failure (TLF) (composite endpoint consisting of cardiac death; target vessel-related MI; clinically driven TLR)

- Major adverse cardiac events (MACE; device oriented MACE composite endpoint; composite endpoint consisting of any death; any MI; emergent CABG or clinically indicated TLR)

- Patient-oriented composite endpoint (POCE; patient-oriented MACE; composite endpoint consisting of any death; any MI; any revascularization)

- Periprocedural MI rates according to alternative definitions such as the SCAI definition, the 3rd Universal Definition of MI, or another (then updated) definition will be reported as additional information

- Major bleeding: bleedings that require surgery or blood transfusions, or cerebral hemorrhages) as defined by ARC criteria as well as the Thrombolysis in Myocardial Infarction (TIMI) criteria19:

* Major bleeding (TIMI)

* Type 3 and 5 (ARC)

Incidence of longitudinal stent deformation (LSD) and deliverability

- Angiographic core lab-identified LSD, as previously defined (von Birgelen et

al., Lancet 2014); mechanisms (compression and/or elongation), characteristics,

clinical outcome

- Operator-reported LSD

- Deliverability of the assigned study stent

Patient-reported chest pain score (CPS)

- Prevalence of patient-reported chest pain at annual follow-up

- Chest pain score at annual follow-up (definitions in analogy with the DUTCH

PEERS TWENTE II 2- year analysis, reported by Sen et al. in JACC Cardiovasc

Interv. 2015; 8: 889-899.)

- Changes thereof over time

- The cumulative incidence

- Relation with coronary revascularizations and with MACE and POCE

Patient-reported dyspnea score (DPS)

- Prevalence of patient-reported dyspnea at the predefined moments of follow-up

Secondary endpoints (except LSD) will be assessed annually.

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 advers events also led to the development of DES with bioresorbable 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 bioresorbable polymer DES are increasingly used in clinical practice, data from head-to-head comparisons between bioresorbable polymer DES with a contemporary highly flexible new generation permanent polymer coated DES.

Study objective

The aim of the study is to compare the outcome of the bioresorbable polymer coated stent (ORSIRO) and a new generation permanent polymer coated stent (RESOLUTE ONYX) in an allcomers patient population and non-inferiority setting.

Study design

Prospective, randomized, single-blinded, multicentre trial with 1:1 randomization for drug-eluting stent type, stratified for gender and the presence of diabetes mellitus.

Intervention

One group will receive the ORSIRO stent, the other group will receive the RESOLUTE ONYX stent. All other intervention and procedural characteristics are similar. Both interventions are in accordance with the standard guidelines for PCI and both stents are used for regular treatment outside this study as well.

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

Patients of 18 years and older, requiring PCI for the treatment of significant coronary artery or bypass graft lesions, being eligible for treatment with drug eluting stents according to clinical guidelines and/or the operators' judgement, and capable of providing informed consent. Patients with all clinical syndromes will be enrolled without any exclusion based on number, type, location or lenth of lesions to be treated.

Exclusion criteria

Known intolerance to components of one of the study DES, or known intolerance to antithrombotic and/or anticoagulant therapy that prevents adherence to any dual anti-platelet therapy (DAPT).
Planned elective surgical procedure necessitating interruption of DAPT during the first 3 months after randomization.
Participation in another randomized cardiovascular device trial or randomized pharmacological study related to antithrombotic and/or anticoagulant therapy before reaching the primary endpoint. Known pregnancy, adherence to scheduled follow-up is unlikely, or life expectancy is assumed to be less than 1 year

Study design

Design

Study phase:	4
Study type:	Interventional
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):	07-10-2015
Enrollment:	1970
Type:	Actual

Medical products/devices used

Generic name:	ORSIRO / RESOLUTE ONYX
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-08-2015
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	17-09-2015
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	01-10-2015

Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	26-01-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	09-06-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	23-09-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	07-02-2017
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	05-03-2019
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
ClinicalTrials.gov	NCT02508714
CCMO	NL54076.044.15