Onyx ONE Study; A Randomized Controlled Trial with Resolute Onyx in One Month DAPT for High-Bleeding Risk Patients

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The purpose of this study is to evaluate the clinical safety and effectiveness of the Resolute Onyx stent in subjects deemed at high risk for bleeding and/or medically unsuitable for more than 1 month DAPT treatment receiving reduced duration (1…

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

Summary

ID

NL-OMON50309

Source
ToetsingOnline

Brief title
Onyx ONE-study

Condition

- Coronary artery disorders

Synonym
angina pectoris, Ischemic heart disease

Research involving
Human

Sponsors and support

Primary sponsor: Medtronic B.V.

Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: DAPT, DES, High bleeding risk patients, PCI

Outcome measures

Primary outcome

To evaluate the clinical safety of the Resolute Onyx stent as compared to the BioFreedom stent with use of 1month DAPT in subjects deemed at high risk for bleeding and/or medically unsuitable for more than 1 month DAPT treatment.

Secondary outcome

To evaluate the clinical effectiveness of the Resolute Onyx stent as compared to the BioFreedom stent with use of 1 month DAPT in subjects deemed at high risk for bleeding and/or medically unsuitable for more than 1 month DAPT treatment.

Study description

Background summary

See protocol section 3.0 for more information in depth.

Both ESC and ACC guidelines acknowledge that there is limited clinical evidence of dedicated DAPT studies in HBR patients, especially with existing stents. Therefore, there is a strong need for randomized trials that evaluate the optimal DAPT duration in HBR patients undergoing implantation of current generation DES

Study objective

The purpose of this study is to evaluate the clinical safety and effectiveness of the Resolute Onyx stent in subjects deemed at high risk for bleeding and/or medically unsuitable for more than 1 month DAPT treatment receiving reduced

duration (1 month) of DAPT following stent implantation

Study design

The Onyx ONE Study is a prospective, multi-center, blinded, post-market interventional, randomized, controlled study enrolling eligible subjects at qualified centers worldwide. The enrollment period is anticipated to be approximately 14 months. Subjects will remain in the study with follow-up clinical assessments through 2 years, study exit, or death, whichever comes first. The population will consist of subjects with coronary artery disease undergoing stent implantation with one of the following commercially available stents and Dual Anti-platelet Therapy through one month: Resolute Onyx (Drug eluting stent, Medtronic) or BioFreedom (Drug coated stent, Biosensors International)

Intervention

Screening and implant (index)PCI procedure;
Subjects will be randomized at a 1:1 ratio to treatment with Resolute Onyx stent or the BioFreedom stent (control).

Clinic visit health status assessment:
* 1 month Subject contact health status assessments (the subject will be assessed by telephone, e-mail, or office visit):
* 2 months
* 6 months
* 1 year
* 2 years

Angiography should be performed for any post-procedure clinical event (e.g., MI) to determine if the event is attributable to the target vessel or a non-target vessel. The reason for any repeat angiography (either clinically driven or non-clinically driven) must be documented on the electronic case report form (eCRF)

Study burden and risks

The potential risks do not differ from the risks associated with the conventional/routine PCI DES implantation procedures described in the Dutch heart foundation.

Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All subjects who are acceptable candidates for treatment with a DES in accordance with applicable guidelines for percutaneous coronary interventions, per manufacturer*s Instructions for Use (and for Australia per IB) who additionally meet pre-defined criteria for being high-bleeding risk and are candidates for 1-month DAPT
To qualify as high-bleeding risk and/or a candidate for 1-month DAPT, subject must meet at least one of the following criteria, -Adjunctive oral anticoagulation treatment planned to continue after PCI
* Age * 75 years old * Baseline Hgb <11 g/dl (or anemia requiring transfusion during the 4 weeks prior to randomization) * Any prior documented intracerebral bleed
* Any documented stroke in the last 12 months
* Hospital admission for bleeding during the prior 12 months
* Non-skin cancer diagnosed or treated *3 years * Planned daily NSAID (other than aspirin) or steroids for *30 days after PCI
* Planned surgery that would require interruption of DAPT (within the next 12

months)
* Renal failure defined as: Creatinine clearance <40 ml/min
* Thrombocytopenia (PLT <100,000/mm3)
* Severe chronic liver disease defined as: subjects who have developed any of the following: variceal hemorrhage, ascites, hepatic encephalopathy or jaundice
* Expected non-compliance to prolonged DAPT for other medical reasons

Exclusion criteria

* Subjects requiring a planned PCI procedure after one month of index procedure
* Subject with planned surgery or procedure necessitating discontinuation of DAPT within one month following index procedure
* Subject not expected to comply with long-term single antiplatelet therapy.
* Subjects with life expectancy of less than two years

Study design

Design

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):	26-02-2018
Enrollment:	300
Type:	Actual

Medical products/devices used

Generic name:	Resolute Onyx Zotarolimus-Eluting Coronary Stent System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-01-2018
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	06-02-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	22-05-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	29-05-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	13-09-2018
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	07-04-2020
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

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	NCT03344653
CCMO	NL63642.075.17