A Prospective, Randomized, Multi-center Study to Assess the SaFety of the Orsiro Mission Stent compared to the ResoLute Onyx Stent in Subjects at High Risk for Bleeding in combination With 1-month Dual Antiplatelet Therapy (DAPT).

Published: 05-07-2021
Last updated: 17-01-2025

To assess the safety of the Orsiro Mission Stent System in subjects at high bleeding risk (HBR) undergoing PCI followed by 30-days Dual Antiplatelet Therapy (DAPT).

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

Summary

ID

NL-OMON52323

Source
ToetsingOnline

Brief title
BIOFLOW-DAPT study

Condition

- Coronary artery disorders

Synonym
Occlusion of bloodvessel(s) in the heart and a high risk for bleedings.

Research involving
Human

Sponsors and support

Primary sponsor: BIOTRONIK AG
Source(s) of monetary or material Support: BIOTRONIK AG

Intervention

Keyword: Coronary Artery Disease (CAD), Dual antiplatelet therapy (DAPT), high bleeding risk (HBR), Percutaneous coronary intervention (PCI)

Outcome measures

Primary outcome

Composite of cardiac death, myocardial infarction (MI) and definite or probable

stent thrombosis at 12 months post index procedure in High Bleeding (risk

(HBR) patients treated with either Orsiro Mission stent or with the Resolute

Onyx stent in combination with 30-days Dual Antiplatelet Therapy (DAPT)

regimen.

Secondary outcome

Additional endpoints will be measured at the 1-, 6-, and 12-month Follow ups:

* Rate of definite/probable stent thrombosis (ST) utilizing the Academic

Research Consortium-2 (ARC-2) definition.

* Rate of major adverse cardiac & cerebrovascular events (MACCE), defined as

the composite of all-cause death, MI, and stroke.

* Rate of major adverse cardiac events (MACE), defined as the composite of

cardiac death, MI, and Target Vessel Revascularization (TVR).

Please see protocol paragraph 4.8 for the complete list of secondary endpoints.

Study description

Background summary

Drug-eluting stents (DES) have significant advantages over bare metal stents (BMS) in the treatment of Coronary Artery Disease (CAD). The introduction of DES greatly reduced the incidence of restenosis and resulted in a better safety profile compared to BMS with systemic drug administration. However, certain clinical events were reported more frequently for DES compared to BMS, especially late and very late stent thrombosis (ST).

Due to the potential for increased risk of ST with DES, the recommended duration of Dual Antiplatelet Therapy (DAPT) was typically longer with DES compared to BMS. Some meta-analyses found a significantly higher risk of bleeding and all-cause mortality associated with a longer DAPT regimen in comparison to a shorter DAPT regimen. Review also found a strong evidence of reduced cardiovascular events at the expense of increased bleeding. Therefore, further studies for subjects with a high bleeding risk were performed to determine whether short DAPT regimen was appropriate considering the higher bleeding risk (HBR) associated with longer DAPT regimen.
The current European guidelines for cardiology favors a shorter duration of DAPT (1-3 months) over a longer DAPT regimen for patients at high risk of bleeding who receive a DES.

see also protocol paragraph 1

Study objective

To assess the safety of the Orsiro Mission Stent System in subjects at high bleeding risk (HBR) undergoing PCI followed by 30-days Dual Antiplatelet Therapy (DAPT).

Study design

Prospective, randomized, muli-center study

Intervention

One group is randomized to receive the Orsiro Mission Drug-eluting stent (DES), the other group is randomized to receive the Resolute Onyx DES stent. Both groups will receive a 30-day Dual Antiplatelet Therapy (DAPT).

Study burden and risks

An in office or telephone contact is done at 1-, 6-, and 12-months after stent

implantion where two health questionnaires are administered (EQ5D & SAQ7) next to the standard clinical assessments.

In case a medication diary is used this will take extra time. The use of a diary is however not mandatory. .

Potential adverse events related to shortening DAPT after stent implantation may include but are not limited to increased risk of stent thrombosis, myocardial infarction or cardiac death.

Contacts

Public
BIOTRONIK AG

Ackerstrasse 6
Bulach CH-8180
CH
Scientific
BIOTRONIK AG

Ackerstrasse 6
Bulach CH-8180
CH

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- An acceptable candidate for treatment with a Drug Eluting Stent (DES)

- Considered at high bleeding risk
- >= 18 years old

Exclusion criteria

- previously experienced stent or scaffold thrombosis in any coronary vessel.
- Revascularization of any target vessel within 9 months prior to the index procedure or previous PCI of any non-target vessel within 72 hours prior to or during the index procedure.
- judged by physician as inappropriate for discontinuation from DAPT at 1 month following index procedure, due to another condition requiring chronic DAPT.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	22-09-2021
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Orsiro Mission stent or Resolute Onyx Stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	05-07-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	21-03-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NCT04137510
CCMO	NL75712.058.21

Study results

Date completed:	12-09-2022

Results posted:	04-09-2023
Actual enrolment:	1

First publication
15-08-2023