MAnagement of high bleeding risk patients post bioresorbable polymer coated STEnt implantation with an abbReviated versus prolonged DAPT regimen

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Interventional

Summary

ID

NL-OMON50683

Source
ToetsingOnline

Brief title
Master DAPT

Condition

- Heart failures

Synonym
haert attack, HBR patienten, stent

Research involving
Human

Sponsors and support

Primary sponsor: European Cardiovascular Research Institute (ECRI-9) bv
Source(s) of monetary or material Support: Sponsor: ECRI-9; non-profit organisatie,Terumo

Intervention

Keyword: bioresorbable-stent, DAPT, high bleedingrisk

Outcome measures

Primary outcome

This study has 3 primary endpoints:

1) Net adverse clinical endpoints (NACE) defined as a composite of all-cause death, myocardial infarction, stroke and bleeding events defined as BARC 3 or 5

2) Major adverse cardiac and cerebral events (MACCE) defined as a composite of all-cause death, myocardial infarction and stroke

3) Major or clinically relevant non-major bleeding (MCB) defined as a composite of type 2, 3 and 5 BARC bleeding events

The main analyses evaluate the occurrence of the primary endpoints between randomization and 11 months thereafter. In secondary analyses, the occurrence of primary endpoints between randomization and 15 months after index PCI is evaluated.

Secondary outcome

The secondary endpoints of the study are the following:

1) The individual components of each composite primary endpoints

2) The composite of cardiovascular death, MI, and stroke

3) The composite of cardiovascular death, MI, and any revascularization

4) Death from cardiovascular causes

5) The composite of definite or probable stent thrombosis

6) Myocardial infarction

7) Any target vessel revascularization

8) Urgent target vessel revascularization

9) Urgent non-target vessel revascularization

10) Clinically indicated non-target vessel revascularization

11) Bleeding events according to the BARC, TIMI and GUSTO classification

12) Transfusion rates both in patients with and/or without clinically detected

over bleeding

Study description

Background summary

High bleeding risk population represents a significant proportion of coronary artery disease (CAD) patients undergoing coronary stent implantation. Decisions regarding the duration of dual antiplatelet therapy (DAPT) after stent implantation are difficult, especially after implantation of newer generation drug eluting stents (DES) due to conflicting results from recent trials.
The current ESC guidelines of myocardial revascularization indicate that in patients at high bleeding risk (HBR), shorter DAPT duration (<6 months) might be considered after DES implantation (Class of recommendation: IIb). Similarly, the more recent American guidelines on DAPT duration, stated that in patients treated with DAPT after DES implantation who develop a high risk of bleeding (e.g., treatment with oral anticoagulant therapy), are at high risk of severe bleeding complication (e.g., major intracranial surgery), or develop significant overt bleeding, discontinuation of P2Y12 inhibitor therapy after 3 or 6 months may be reasonable (Class of recommendation IIb). Both the European and American guidelines acknowledge that limited data is currently available to sustain this practice and call for dedicated DAPT studies in HBR patients.
Therefore, further randomized trials are needed to appraise the optimal DAPT duration in HBR patients treated with contemporary DES.

Study objective

The objective is to compare, within current guidelines (GL) and instructions

for use (IFU), an abbreviated versus a prolonged DAPT duration after bioresorbable polymer coated Ultimaster sirolimus-eluting stent implantation in patients presenting HBR features.

Study design

Een onderzoeker-geïnitieerd, multi center, gerandomiseerde klinische proef in HBR patiënten na PCI, met Ultimaster bioresorbable polymeer sirolimus-eluerende gecoate stent implantatie.

Intervention

One group of patients will receive after placement of the stent a shorter treatment with anti-coagulant medication; the other group will receive a longer treatment with anti-coagulant medication.

Study burden and risks

To improve patient standard care, there will be 3 point of contacts 1 on site visit during which the medication regime, anginaal status and adverse events are discussed and monitored.

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

Inclusion criteria after index PCI
After index PCI, patients aged 18 years or more are eligible for inclusion into the study if the following criteria are met.
1) At least one among the HBR criteria (as defined below) is met.
2) All lesions are successfully treated with Ultimaster stent in the context of routine clinical care, i.e. post-procedural angiographic diameter stenosis <20% by visual estimation
3) Free from any flow-limiting angiographic complications (i.e. significant untreated dissection or major side-branch occlusion), which require prolonged DAPT duration based on operator*s opinion.
4) All stages of PCI are complete (if any) and no further PCI is planned.
Inclusion criteria at one-month randomization visit
At randomization visit (one month after index PCI), the following criteria must be met:
1) Fulfilment of at least one HBR criterion (as defined below), or on the basis of post-PCI actionable (i.e. requiring medical attention) non-access site related bleeding episode
2) Uneventful 30-day clinical course, i.e. free from spontaneous MI, symptomatic restenosis, stent thrombosis, stroke and any revascularization (coronary and non-coronary) requiring prolonged DAPT
3) If not on OAC,
a. Patient is on a DAPT regimen of aspirin and a P2Y12 inhibitor
b. Patient with one type of P2Y12 inhibitor for at least 7 days (i.e. no switching between oral P2Y12 inhibitors has occurred in the previous 7 days)
4) If on OAC
a. Patient is on the same type of OAC (e.g. Vitamin K antagonist or NOAC) for at least 7 days
b. Patient is on clopidogrel for at least 7 days

Exclusion criteria

Patients are not eligible if any of the following applies
1) Treated with stents other than Ultimaster stent within 6 months prior to index procedure
2) Treated for in-stent restenosis or stent thrombosis at index PCI or within 6 months before
3) Treated with a bioresorbable scaffold at any time prior to index procedure
4) Cannot provide written informed consent
5) Under judicial protection, tutorship or curatorship
6) Unable to understand and follow study-related instructions or unable to comply with study protocol
7) Active bleeding requiring medical attention (BARC>=2) on randomization visit
8) Life expectancy less than one year
9) Known hypersensitivity or allergy for aspirin, clopidogrel, ticagrelor, prasugrel, cobalt chromium or sirolimus
10) Any planned and anticipated PCI
11) Participation in another trial
12) Pregnant or breast feeding women

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-04-2017
Enrollment:	550
Type:	Actual

Ethics review

Approved WMO Date:	25-01-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	01-04-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	24-07-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL59979.101.16