Improved drug eluting stent for percutaneous coronary intervention of the left main artery in a real world all-comers population

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

Summary

ID

NL-OMON47380

Source
ToetsingOnline

Brief title
IDEAL LM

Condition

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

Synonym
Narrowing left main artery

Research involving
Human

Sponsors and support

Primary sponsor: Golden Jubilee National Hospital, National Times Waiting Board
Source(s) of monetary or material Support: Niet commerciële sponsor: Golden Jubilee National Hospital;National Times Waiting Board

Intervention

Keyword: Drug eluting stent, Left main artery, Percutaneous coronary intervention

Outcome measures

Primary outcome

The primary endpoint is MACE rate, including death from any cause, MI, or ischemia-driven target vessel revascularization (TVR) at 2 years after the procedure.

Secondary outcome

• The individual events of the primary endpoint

• Procedure success (attainment of <30% residual stenosis of the target lesion and no in-hospital DoCE).

• Device-oriented Composite Endpoints at 1 month and 6 months and annually to 3 years and its individual components. Device-oriented Composite Endpoint (DoCE) is defined as cardiac death, MI not clearly attributable to a non- intervention vessel, and clinically-indicated target lesion revascularization.

• Stent thrombosis according to ARC definition at all time points.

• The composite of BARC 3 or 5 bleeding at 24 months according to BARC definition

• The individual bleeding events (BARC 1, 2, 3, 4 and 5) according to the BARC definition

Study description

Background summary

Patients with unprotected left main coronary artery (uLMCA) lesions benefit from revascularisation. Over the years coronary artery bypass graft (CABG) surgery has been the preferred strategy. With improved percutaneous coronary intervention (PCI) techniques this procedure has become extremely safe with good long term outcomes in patients with non-complex disease. uLMCA has been a contra indication for PCI for many years. With the introduction of stents for a predictable acute outcome uLMCA has become feasible, but was still limited by the frequently needed repeat procedures due to in-stent restenosis. This has been improved with the use of drug-eluting stents (DES) and uLMCA PCI has been accepted in the ESC guidelines for several patients groups. DES technology has continuous been improved and several studies has demonstrated superiority of new designs over the first generation DES.
In the previous studies using the first generation drug-eluting stent, a significant association was observed between discontinuation of dual antiplatet therapy and the occurrence of thrombotic events in the first 6 or 12 months. Based on these findings, the current ESC guidelines therefore recommends 6-12 months after drug-eluting stent implantation. However, the recent randomized trials using 2nd generation drug-eluting stent (everolimus-eluting or zotarolimus eluting) demonstrated no benefits favouring prolonged dual antiplatelet therapy while many shortcomings have been found with prolonged DAPT therapy including bleeding and cost issues. In the PRODIGY study (Prolonging Dual Antiplatelet Treatment After Grading Stent-Induced Intima Hyperplasia Study), the primary outcome (all- cause mortality, MI, or stroke) was similar between 6 or 24 month DAPT therapy. More recently, the OPTIMIZE trial (Optimized Duration of Clopidogrel Therapy Following Treatment With the Zotarolimus-Eluting Stent in Real-World Clinical Practice) showed that in patients with stable coronary artery disease or low-risk ACS treated with zotarolimus-eluting stents, 3 months of dual antiplatelet therapy was non-inferior to 12 months for net clinical adverse and cerebral events, without significantly increasing the risk of stent thrombosis. These trials suggest that the short DAPT therapy (3 months) could be safe after implantation of 2nd generation drug-eluting stent.

Study objective

The primary objective is to establish the non-inferiority of the Synergy stent relative to the Xience stent for prevention of MACE. The effect measure is the difference in the rate of MACE in patients randomized to treatment with the Synergy (index) stent (r1) to that in patients randomized to treatment with the Xience (control) stent (r0). The null hypothesis is that the risk difference (r1-r0) is larger than or equal to the specified non-inferiority

margin of 7.5%. The alternative hypothesis is that the difference in the MACE rate is less than 7.5%. The null-hypothesis of inferiority of the Synergy stent to the XIENCE stent will be rejected if the upper bound of 95% confidence interval of risk difference (r1-r0) falls below 7.5%.

Study design

This is a prospective, randomized, multicenter study in patients with an indication for coronary artery revascularisation who have been accepted for percutaneous coronary intervention (PCI) of the left main coronary artery. Patients who are scheduled to undergo standard PCI of the left main coronary artery will be randomized in a 1:1 fashion to the Synergy stent arm or to XIENCE stent arm. Dual antiplatelet therapy (DAPT) will be stopped at t=4 months in the Synergy arm whereas in the control arm DAPT will be continued for 12 months.
A subgroup of 100 patients will have control angiography with Optical Coherence Tomography (OCT) at t=3 months after treatment.
Total clinical follow-up will be 5 years.

Intervention

Patients who are scheduled to undergo standard PCI of the left main coronary artery will be randomized in a 1:1 fashion to the Synergy stent arm or to XIENCE stent arm. Dual antiplatelet therapy (DAPT) will be stopped at t=4 months in the Synergy arm whereas in the control arm DAPT will be continued for 12 months.

Study burden and risks

Because this study follows normal clinical practice, there is no presumption that there are additional disadvantages or risks for participation. The risks of the procedures that are part of standard care are explained.

For sub-study group:
After 3 months to undergo two additional procedures, this will expose the patient to more radiation than when a patient would not participate in this study. This additional risk is assessed by an expert who has nothing to do with the investigation. This has calculated that the risk is equivalent to almost 38 months of background radiation. This represents an additional risk of 1 in 2900 for fatal cancer.

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

1. Patient has an indication for coronary artery revascularisation of the left main artery in accordance with the ESC guidelines
2. Patient has been discussed with the cardiac surgeon prior to PCI procedure
3. Patient is accepted for PCI
4. Patient is at least 18 years of age.
5. The patient understands and accepts the meaning and the aims of the study and is willing to provide written informed consent
6. The patient is willing to comply with specified follow-up evaluation and can be contacted by telephone.

Exclusion criteria

1. Not able to receive anti-platelet treatment due to contraindications
2. Known allergy to acetylsalicylic acid, clopidogrel, prasugrel or ticagrelor
3. Cardiogenic shock

4. STEMI within the last 5 days
5. Planned surgery within 12 months after stent introduction
6. History of bleeding diathesis or active major bleedings
7. Major surgery within previous 15 days
8. Current participation in another trial which has not yet reached its primary endpoint
9. Life expectancy < 12 months
10. Hypersensitivity or contraindication to everolimus or structurally-related compounds, cobalt, chromium, nickel, tungsten, acrylic, platinum and fluoropolymers
11. Female patient with child bearing potential not taking adequate contraceptives or currently breastfeeding

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-07-2015
Enrollment:	55
Type:	Actual

Medical products/devices used

Generic name:	Drug eluting stent
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	22-06-2015
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	04-09-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	06-03-2019
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL51314.078.14