Optical coherence tomography-guided PCI with single antiplatelet therapy

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

Summary

ID

NL-OMON55165

Source
ToetsingOnline

Brief title
OPTICA

Condition

- Coronary artery disorders

Synonym
'acute coronary syndrome', 'heart attack'

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Abbott,Academisch Medisch Centrum,Werfen B.V.

Intervention

Keyword: antiplatet therapy, percutaneous coronary intervention, prasugrel, ticagrelor

Outcome measures

Primary outcome

The primary ischemic endpoints at 6 months is the composite of:

- All-cause mortality

- Myocardial infarction (according to the 4th universal definition of MI)

- Academic Research Consortium (ARC) defined definite or probable stent thrombosis

- Ischemic stroke

The primary bleeding endpoint at 6 months is:

- Major or minor bleeding defined as Bleeding Academic Research Consortium (BARC) type 2, 3 or 5 bleeding

Secondary outcome

The secondary endpoints are:

- Primary ischemic and bleeding endpoint at 12 months

- Each individual component of the primary endpoints at 6 and 12 months

- Cardiovascular mortality at 6 and 12 months

- Non-cardiovascular mortality at 6 and 12 months

- Any need for revascularization at 6 and 12 months

- Any periprocedural complications

- On-treatment platelet reactivity at baseline

Study description

Background summary

Approximately 15,000 patients with non-ST-segment elevation acute coronary syndrome (NSTE-ACS) are admitted to Dutch hospitals each year. Most of these patients are treated with percutaneous coronary intervention (PCI) using intracoronary stents. Dual antiplatelet therapy (DAPT), consisting of aspirin and a P2Y12-inihibitor, reduces the risk of stent thrombosis, myocardial infarction (MI) and stroke as compared to aspirin alone after coronary stent implantation. However, DAPT inevitably increases the risk of major bleeding events, which in turn is associated with increased mortality, morbidity and reduced quality of life (all associated with very high healthcare costs). In recent decades, improvements in stent designs, interventional techniques and antithrombotic therapies have substantially reduced the risk of stent thrombosis and subsequent ischemic complications.

Among these improvements is the development of new generation drug-eluting stents (DES). The bulky, thick-strut bare-metal stents (BMS) that were used when DAPT was introduced, have therefore become obsolete. The advent of safer, new generation DES equipped with biocompatible coatings has led to low rates of stent thrombosis. These DES are now commonly used in all patients. Pharmacological therapy has improved as well. New potent P2Y12-inhibitors, i.e. prasugrel and ticagrelor, have been shown to significantly reduce the incidence of stent thrombosis as compared to clopidogrel. These novel agents are currently used alongside aspirin as the standard-of-care for acute coronary syndrome (ACS).

These combined innovations in the field of interventional cardiology have opened the door for single antiplatelet strategies. Previous randomized controlled trials (RCT) have already shown the effects of a single antiplatelet strategy with potent P2Y12-inhibitors, but this always involved concurrent aspirin use during at least 1-3 months. A recent meta-analysis of four trials investigating P2Y12-inhibitor monotherapy after PCI concluded that P2Y12-inhibitor monotherapy preceded by a short period of DAPT was associated with a lower incidence of clinically relevant bleeding compared to standard DAPT without a significant differences in cardiovascular events after one year.

Study objective

The primary objective of this study is to assess the feasibility and safety of a single antiplatelet strategy with prasugrel or ticagrelor prior to, during and after PCI with a new generation drug-eluting in non-ST-elevation acute coronary syndrome patients

Study design

Single-center, single-arm pilot study

Intervention

Prasugrel or ticagrelor monotherapy prior to, during and 12 months after percutaneous coronary intervention

Study burden and risks

In addition to standard care, patients will undergo platelet function testing with VerifyNow prior to the procedure, which requires an additional blood draw. Furthermore, the first 35 patients will undergo optical coherence tomography assessment after stent implantation. Patients will be contacted by phone at 1, 3, 6 and 12 month(s) after stent implantation for follow-up. Single antiplatelet therapy may lead to a reduction in (major) bleeding events, while reducing the number of medications patients use. However, it is unknown if single antiplatelet therapy effects the risk of thrombotic complications (e.g. stent thrombosis).

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

- Age >=18 years
- NSTE-ACS diagnosis in accordance with relevant guidelines
- *De novo* coronary lesion(s) eligible for PCI using new generation drug-eluting stent and requiring revascularization according to relevant guidelines
- Written informed consent

Exclusion criteria

- Known allergy or contraindication for prasugrel or ticagrelor use
- Concurrent use of oral anticoagulants (e.g. for atrial fibrillation)
- Overwriting indication for DAPT (e.g. recent PCI or ACS)
- Planned surgical intervention within 12 months of planned revascularization
- PCI of left main disease, chronic total occlusion, bifurcation lesion requiring two-stent treatment, saphenous or arterial graft lesion, severely calcified lesions
- Recent or ongoing treatment with a strong CYP3A4 inhibitor or inducer
- Pregnant or breastfeeding women at time of enrolment
- Participation in another trial with an investigational drug or device (i.e. stent)

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-03-2021
Enrollment:	75
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Aspirin
Generic name:	Acetylsalicylic acid
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Brilique
Generic name:	Ticagrelor
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Efient
Generic name:	Prasugrel
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	23-12-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	29-01-2021
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	12-02-2021

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-05-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-06-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	09-10-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-11-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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
EudraCT	EUCTR2020-003437-38-NL
ClinicalTrials.gov	NCT04766437
CCMO	NL74724.018.20