Prospective, randomized, open label trial of six vs. twelve months dual antiplatelet therapy after drug-eluting stent implantation in ST-elevation myocardial infarction.

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To test the hypothesis that 6 months DAPT after second generation DES implantation in STEMI is not inferior to 12 months DAPT in terms of clinical outcomes (composite endpoint of all-cause mortality, any MI, any revascularization, stroke and major...

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

Summary

ID

NL-OMON39800

Source
ToetsingOnline

Brief title
DAPT-STEMI

Condition

- Coronary artery disorders

Synonym
DAPT treatment after PCI, Dual-antiplatelettherapy after stent implantation

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: Medicines Company,Medtronic,unrestricted grant van Medtronic en de Medicine Company

Intervention

Keyword: DAPT/PCI/ST-Elevation-MI/Randomisation

Outcome measures

Primary outcome

DAPT STEMI trial

Composite endpoint of all cause mortality, any MI, any revascularization,

stroke, ST and Bleeding (TIMI) (net MACCE) at 18 months after randomization

Registry Bivilarudine/Prasugrel and Bivlarudine/Ticagrelor

All cause mortality, MI, Stroke, ST and bleeding (following BARC) at 2 and 30

days.

Report Resolute Integrity

Primary endpoint of DAPT-STEMI, at 30 days and 6 months.

Secondary outcome

DAPT-STEMI trial

• All cause mortality, any MI, stroke, stent thrombosis (ST) and major bleeding

(TIMI) at 9 and 18 months after randomization

• ST definite/probable academic research consortium (ARC) definition at 9, and

18 months post randomization

• All cause mortality at 9 and 18 months after randomization

• Cardiac mortality at 9 and 18 months after randomization

• Any MI at 9 and 18 months after randomization

• Target vessel MI at 9 and 18 months after randomization

• Bleeding at 9 and 18 months after randomization

• Stroke at 9 and 18 months after randomization

• Target vessel revascularization (TVR) at 9 and 18 months after randomization

• Target lesion revascularization (TLR) at 9 and 18 months after randomization

• Target vessel failure (TVF) at 9 and 18 months after randomization.

• Target lesion failure (TLF), at 9 and 18 months after randomization

Registry

• ST following ARC definition at 2 and 30 days.

• All cause mortality at 2 and 30 days.

• Cardiac mortality at 2 and 30 days.

• All MI at 2 and 30 days.

• Target vessel MI at 2 and 30 days.

• Bleeding (BARC) at 2 days.

• Stroke at 2 days.

Report Resolute Integrity

• Identical to DAPT-STEMI, at 30 days and 6 months

Study description

Background summary

First generation DES (Drug Eluting Stents) have significantly reduced the restenosis rates compared to the BMS but have raised concerns regarding higher rates and ongoing propensity for stent thrombosis. Based on these concerns current guidelines advocate dual antiplatelet therapy (DAPT, aspirin plus P2Y12 inhibitor) to be continued for up to1 year after DES implantation. Large registries analyzing recent data now challenge these recommendations and suggest no increase in mortality or (late) stent thrombosis when DAPT is discontinued after 6 months.

Study objective

To test the hypothesis that 6 months DAPT after second generation DES implantation in STEMI is not inferior to 12 months DAPT in terms of clinical outcomes (composite endpoint of all-cause mortality, any MI, any revascularization, stroke and major bleeding at 18 months after randomization). The trial will incorporate two registers studying respectively the safety outcomes of Bivalirudin and Prasugrel combination and Bivalirudin and Ticagrelor combination at 2 and 30 days. Finally the trial design permits assessment of the clinical outcomes after primary PCI for treatment of STEMI with the new Resolute Integrity (Medtronic Santa Rosa Ca, USA) stent at 30 days and 6 months.

Study design

This is a prospective, randomized, open-label trial testing the hypothesis that 6 months DAPT after second generation drug eluting stent (DES) implantation in STEMI is not inferior to 12 months DAPT in terms of clinical outcomes. Patients with STEMI undergoing primary PCI will be enrolled at presentation. Only those patients who are event-free (death, MI, ST, TVR/TLR or unscheduled revascularization with DES in the first 6 months and stroke or bleeding requiring discontinuation of DAPT) and on DAPT at 6 months after primary PCI will be randomized (1:1 fashion) between single (aspirin) versus dual antiplatelet therapy (aspirin plus P2Y12) for an additional 6 months (up to 12 months after primary PCI) and assessed at 18 months post randomization.

Intervention

Patients, who are event-free and stil on DAPT at 6 months after primary PCI will be randomized (1:1 fashion) between single (aspirin) versus dual antiplatelet therapy (aspirin plus P2Y12) for an additional 6 months (up to 12 months after primary PCI).

Study burden and risks

The study investigates a treatment strategy (6 months DAPT versus 12 months DAPT).
In case the patient is randomised to the patientgroep, that will be treated during 12 months with a combination of 2 antiplatelet drugs, there may be an increased risk on bleedings.
In case the patient is randomised to the patientgrope, that after 6 months will on ly be treated with one antiplatelet drug, there may be an increased risk on thrombosis/cardiovascular complications.
See also section 10.4 of the protocol.

Burden for the patient:
It is possible that the patient has to come for an extra out-clinic visit for the randomisation at 6 months. However it is also possible that this can be combined with a routine out-clinic visit. Besides the patient will be approached with a standard questionnaire three times during the course of the study.

Contacts

Public
Maasstadziekenhuis

Maasstadweg 21
Rotterdam 3079DZ
NL
Scientific
Maasstadziekenhuis

Maasstadweg 21
Rotterdam 3079DZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

STEMI patients between 18-85 years, who underwent PCI with second generation DES implantation

Exclusion criteria

Key Exclusion Criteria Enrollment: Intolerance to Aspirin, Plasugrel, Ticagrelor, Heparin, Bivaluridin, Everoliumus or Zotarolimus.
Known bleeding diathesis or known coagulopathy.
Planned elective surgical procedure necessitating interruption of dual antiplatelet therapy during the first 6 months after randomization.;Key Exclusion Criteria Randomization:
Occurrence of death, myocardial infarction, stent thrombosis and target vessel or lesion revascularization during the first 6 months after inclusion.
Stroke or bleeding requiring discontinuation of DAPT during the first 6 months after inclusion.
Oral anticoagulant therapy with coumarin derivates.

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:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-12-2011

Enrollment:	580
Type:	Actual

Ethics review

Approved WMO Date:	15-08-2011
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	06-07-2012
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	04-09-2012
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	11-04-2013
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	13-01-2014
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	13-03-2014
Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)
Approved WMO Date:	26-06-2014

Application type:	Amendment
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (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	NL37256.101.11

Study results

Date completed:	01-07-2017
Actual enrolment:	580

Summary results
Trial is onging in other countries