Randomized Evaluation of short-term DUal anti platelet therapy in patients with acute coronary syndrome treated with the COMBO dual-therapy stEnt

Published: 14-01-2014
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To evaluate safety of 3-months versus standard 12-months of DAPT

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

Summary

ID

NL-OMON41374

Source
ToetsingOnline

Brief title
REDUCE

Condition

- Myocardial disorders

Synonym
acute coronary syndrom, obstruction blood vessel of the heart

Research involving
Human

Sponsors and support

Primary sponsor: Diagram B.V.
Source(s) of monetary or material Support: Diagram B.V.,OrbusNeich

Intervention

Keyword: ACS, COMBO stent, DAPT

Outcome measures

Primary outcome

All cause mortality, MI, ST, stroke, TVR, bleeding (BARC II, III, V) at 12 months

Secondary outcome

Bleeding (BARC II, III, V) at 12 months

All cause mortality, MI, ST, stroke, TVR, bleeding (BARC II, III, V) at 24 months

All cause mortality, MI, ST, stroke and TVR at 12 and 24 months

Mortality at 12 and 24 months

Cardiac Mortality at 12 and 24 months

Any MI at 12 and 24 months

ST at 12 and 24 months

Repeat revascularization at 12 and 24 months

Time to event as defined by the occurrence of one of the following: all cause mortality, MI, ST, stroke, TVR or bleeding (BARC II, III, V) within 12 and 24 months

Prespecified landmark analysis of Primary Endpoint (without TVR) from 3 to 12 months

Study description

Background summary

The optimal duration of dual antiplatelet therapy in ACS patients treated with DES is still under debate. This is especially true for STEMI patients in the era of new anticoagulants and antiplatelet agents. Yet, the potential benefits of longterm dual antiplatelet therapy in avoiding thrombotic complications may be clearly counterbalanced by a higher risk of major bleeding complications. In particular, the COMBO dual therapy stent, being associated with early re-endothelization, may allow for a reduction of the duration of DAPT without increasing the thrombotic risk, while reducing the risk of severe bleeding complications.

Study objective

To evaluate safety of 3-months versus standard 12-months of DAPT

Study design

Prospective, multicenter, randomized investigator-initiated study designed to enroll 1500 patients with ACS receiving a COMBO stent. Patients will be randomized before discharge into a 1:1 fashion to either 3 or 12 months DAPT. Follow-up is scheduled at 3, 6, 12, and 24 months.

Intervention

intervention: 3 months DAPT
control: 12 months DAPT

Study burden and risks

Antiplatelet therapy helps to prevent blood vessels to occlude/obstruct. A side effect of antiplatelet therapy is that the risk of bleeding complications rises.

The most apparent side effects of Aspirin administration are the following, although they occur infrequently:
- ulcers of the stomach and duodenum (first part of the small intestine)
- abdominal pain
- nausea
- gastritis (inflammation of the stomach)
- even serious gastrointestinal bleeding from ulcers
- occasionally, aspirin may be toxic to the liver

The most apparent side effects of a P2Y12 receptor inhibitor (Clopidogrel, Prasugrel or Ticagrelor) are the following:
- bleeding

- shortness of breath
- ventricular pause
- increase of serum uric acid and serum creatinine

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. The patient must be >=18 years of age
2. The patient has been diagnosed with STEMI, NSTEMI or UA
3. The Patient is willing to comply with specified follow-up evaluations
4. The Patient has been informed of the nature of the study, agrees to its provisions and has been provided written informed consent, approved by the appropriate Medical Ethics Committee (MEC), Institutional Review Board (IRB), or Human Research Ethics Committee (HREC)

5. Successful COMBO stent implantation (TIMI 3 flow with residual stenosis < 20% based visual estimation), with no clinical adverse event during hospitalization (Death, stent thrombosis (ST), stroke, target vessel revascularisation (TVR), bleeding (BARC II, III, V))

Exclusion criteria

1. Patients presenting with cardiogenic shock
2. Patients with recent major bleeding complications or contraindication to DAPT, such as:
a) Hypersensitivity to Aspirin, Clopidogrel, Prasugrel or Ticagrelor
b) Need for oral anticoagulation
c) History of bleeding diathesis or known coagulopathy (including heparin-induced thrombocytopenia) or refusal of blood transfusions
d) History of intracerebral mass, aneurysm, arteriovenous malformation, or hemorrhagic stroke
e) Stroke or transient ischemic attack within the past 6 months or any permanent residual neurologic defect
f) Gastrointestinal or genitourinary bleeding within the last 2 months or major surgery within 6 weeks
g) Recent history (<3 months prior to randomization) or known current platelet count <100 000 cells/mm3 or hemoglobin <10 g/dL
h) An elective surgical procedure is planned that would necessitate interruption of thienopyridines during the first 12 months post enrollment
3. Planned need for concomitant cardiac surgery (e.g., valve surgery or resection of aortic or left ventricular aneurysm etc.)
4. Planned intervention of another lesion (target vessel or non-target vessel) after index hospital discharge
5. Any revascularization performed within index hospitalization with other stents than COMBO
6. Potential for non-compliance towards the requirements in the trial protocol (especially the medical treatment) or follow-up visits
7. Patients requiring permanent DAPT due to comorbidities
8. Patient has received any organ transplant or is on a waiting list for any organ transplant
9. Life expectancy of less than 2 years
10. Pregnancy or intention to become pregnant during the course of the trial
11. Any significant medical or mental condition, which in the Investigator*s opinion may interfere with the patient*s optimal participation in the study
12. Currently participating in another investigational drug or device study
13. Patients who have been treated with another DES within 9 months prior to the index procedure

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:	Recruitment stopped
Start date (anticipated):	05-06-2014
Enrollment:	350
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
Product type:	Medicine
Brand name:	Plavix
Generic name:	Clopidogrel
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	14-01-2014
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	17-04-2014
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	19-06-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	23-06-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	25-11-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	27-11-2014
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	19-05-2015
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	29-05-2015
Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)
Approved WMO Date:	16-09-2015

Application type:	Amendment
Review commission:	METC Isala Klinieken (Zwolle)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20593
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2013-005571-40-NL
ClinicalTrials.gov	NCT02118870
CCMO	NL47464.075.13
OMON	NL-OMON20593