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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20593

Source
NTR

Brief title
REDUCE trial

Health condition

Patienten met ACS (ST-segment elevatie myocard infarct (STEMI, Non-ST-segment elevatie myocard infarct (NSTEMI) of instabiele angina pectoris (IAP) na een succesvolle PCI met COMBO stent implantatie.

Sponsors and support

Primary sponsor: Diagram BV
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

Composite of all cause mortality, Myocardial Infarction (MI), stent thrombosis(ST), stroke, target vessel revascularization (TVR) or bleeding (BARC II, III,V) at 360 days.

Secondary outcome

Bleeding (BARC II, III, V) at 360 days,All cause mortality, MI, ST, stroke, TVR, bleeding (BARC II, III, V) at 360 and 720 days,All cause mortality, MI, ST, stroke and TVR at 360 and 720 days. Mortality at 360 and 720 days,Cardiac Mortality at 360 and 720 days,Any MI at 360 and 720 days,ST at 360 and 720 days,Repeat revascularization at 360 and 720 days,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 360 and 720 days,Prespecified landmark analysis of Primary Endpoint (without TVR) from 90 to 360 days.

Study description

Background summary

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 90 or 360 days DAPT. Follow-up is scheduled at 90 days, 90 days, 360 days, and 720 days.

Study objective

Aim of the current study is to demonstrate a non-inferiority of a strategy of short-term DAPT (90 days) as compared to standard 360 days DAPT in ACS patients treated with Combo stent.

Study design

90 days, 180 days, 360 days, 720 days

Intervention

Intervention: 90 days DAPT
Control: 360 days DAPT

Contacts

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Eligibility criteria

Inclusion criteria

- The patient must be ≥ 18 years of age
- The patient has been diagnosed with STEMI, NSTEMI or UA
- The patient is willing to comply with specified follow-up evaluations
- 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)
- 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

- Patients presenting with cardiogenic shock
- 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 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
- Planned need for concomitant cardiac surgery (e.g., valve surgery or resection of aortic or left ventricular aneurysm etc.)
- Planned intervention of another lesion (target vessel or non-target vessel) after index hospital discharge
- Any revascularization performed within index hospitalization with other stents than COMBO
- Potential for non-compliance towards the requirements in the trial protocol (especially the medical treatment) or follow-up visits
- Patients requiring permanent DAPT due to comorbidities
- Patient has received any organ transplant or is on a waiting list for any organ transplant
- Life expectancy of less than 2 years
- Pregnancy or intention to become pregnant during the course of the trial
- Any significant medical or mental condition, which in the Investigators opinion may interfere with the patients optimal participation in the study
- Currently participating in another investigational drug or device study
- Patients who have been treated with another DES within 9 months prior to the index procedure

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-03-2014
Enrollment:	1500
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	11-02-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 41374
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4241
NTR-old	NTR4386
CCMO	NL47464.075.13
OMON	NL-OMON41374

Study results

Summary results
N/A