Clopidogrel for the prevention of late cardiac events in patients with asymptomatic perioperative acute coronary syndrome.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29444

Source
NTR

Brief title
DECREASE VII

Health condition

English:
Clopidogrel
Cardiac complications
Vascular surgery

Dutch:
Clopidogrel
Cardiale complicaties
Vaatoperaties

Sponsors and support

Primary sponsor: Stichting Lijf en Leven
Source(s) of monetary or material Support: Stichting Lijf en Leven

Intervention

Outcome measures

Primary outcome

The primary objective of this study is to determine whether clopidogrel + best medical treatment is
superior to best medical treatment only in preventing:

A) cardiovascular death, MI, stroke, or severe ischemia of the coronary or peripheral arterial circulation
leading to an intervention in patients with asymptomatic perioperative troponin release during or shortly
after major vascular surgery.

Secondary outcome

Secondary objectives include determining the effect of clopidogrel on:

B) Bleeding complications, defined as life-threatening bleeding, moderate and minor bleeding in patients
with asymptomatic perioperative troponin release after major vascular surgery.

Study description

Background summary

Rationale:

Clopidogrel on top of standard treatment with aspirin has
been proven to be
effective and safe for the treatment and prevention of Acute Coronary
Syndromes (ACS).
In vascular surgical patients who have asymptomatic perioperative
myocardial ischemia
(PMI) measured by troponin T release no suitable treatment for the
prevention of
cardiovascular events during follow-up is available.

Objective:
To investigate the efficacy and safety of clopidogrel for the

prevention of
cardiovascular events during follow-up in patients with PMI during major vascular
surgery. Furthermore we obtain to identify new preoperative risk factors and novel
biomarkers for the development of cardiovascular events during follow-up after major
vascular surgery.

Study design:
The current study has a open randomized intervention
design, with a 24
months follow-up. Data and blood sample collection will be done pre-operatively
(outpatient clinic), perioperative and 30 days, 3, 6, and 12 months after surgery.

Study population:
The proposed study consists of 750 patients above the
age of 18
years who develop asymptomatic troponin T release after elective major vascular surgery
defined as: (1) abdominal aortic aneurysm (AAA) repair, (2) aortic stenosis repair, (3)
above knee femoropopliteal bypass surgery, and (4) below knee femoropopliteal bypass
surgery. The total study time is 4 years, including 3 years patient inclusion and 1 year
follow-up of the last included patient.

Intervention:
All patients receive standard medical treatment with
aspirin, betablocker,
statin and proton pump therapy. If postoperative troponin T elevation is present, patients
are randomized either to the clopidogrel group and receive a loading dose of 300mg,
followed by a daily dose of 75mg during at least one year. The other group receives the
standard medical treatment.

Main study parameters/endpoints:
The primary outcome is defined as the

composite
of cardiovascular death, MI, stroke, or severe ischemia of the coronary
or peripheral
arterial circulation leading to an intervention during the first 12
months of the follow-up
period. Safety outcomes include life-threatening, moderate bleeding and
minor bleeding
is considered as secondary outcome. Tertiary objectives include
identification of
preoperative risk factors and novel biomarkers of the primary endpoint.

Study objective

Clopidogrel is effetive and safe for the prevention of cardiovascular events during follow-up in patients with Perioperative Myocardial Infarction during major vascular surgery.

Study design

- Troponin T measurement at days 1, 3 and 7 postoperatively.

- Outpatient clinic visits at 30 days, 3, 6, 12 months.
Telephonic or written contact.

Intervention

Randomisation for use of clopidogrel on top of standard treatment with aspirin or use of aspirin only. Randomisation is executed after the patient develops an asymptomatic troponin T release during the perioperative period.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age above 18 years

2. Patients scheduled for major vascular surgery, one of the following:

- Abdominal aortic aneurysm repair

- Aortic stenosis repair

- Femoropopliteal bypass surgery, above and below knee

Exclusion criteria

1. Active bleeding

2. Untreated left main disease

3. Active cardiac condition such as unstable angina pectoris, arrhythmias, symptomatic valvular disease, recent < 6 months.

4. Preoperative positive troponin T

5. Inability to take clopidogrel orally

6. Clear indication for long-term clopidogrel use

7. Previous allergy or intolerance to clopidogrel

8. Renal failure requiring dialysis

9. Significant liver disease (i.e. ALAT, ASAT >3x ULN)

10. Cancer with an expected life expectancy < 6 months

11. Anticipated non-adherence to clopidogrel

12. Excessive alcohol use

13. Pregnancy or planning to become pregnant

14. Failure to provide informed consent

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-12-2008
Enrollment:	750
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 32253
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL1377
NTR-old	NTR1436
CCMO	NL22179.078.08
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON32253

Study results

Summary results
N/A