

# The Rotterdam Antiplatelet Therapy in Vascular Patients Study

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Suspended
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON28641

### Source

Nationaal Trial Register

### Brief title

RAVE

### Health condition

Patients who undergo vascular surgery for abdominal aneurysm or peripheral artery disease who have myocardial injury (e.g. hsTnT release) before and after the procedure.

Patienten die een ingreep ondergaan in verband met een abdominaal aneurysma of perifeer arterieel vaatlijden, met myocard schade (gedefinieerd als hsTnT stijging) voor en na de ingreep.

## Sponsors and support

**Primary sponsor:** Erasmus Medical Center Rotterdam

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

## Intervention

## Outcome measures

### Primary outcome

The primary objective is to assess the efficacy of clopidogrel, as compared to placebo, on top of standard treatment with aspirin on;

A. the composite endpoint of MACE, defined as;

- cardiovascular death
- non-fatal myocardial infarction
- stroke
- severe ischemia of the coronary or peripheral arterial circulation leading to intervention

### **Secondary outcome**

Secondary objectives include determining the efficacy of clopidogrel, compared to placebo, on top of standard treatment with aspirin on;

B. Individual components of MACE

C. Safety of clopidogrel, in terms of bleeding complications, defined as life-threatening bleeding, moderate and minor bleeding, postoperatively and during long-term follow-up.

Tertiary objectives include determining;

D. Presence of significant coronary artery disease and the impact of presence of vulnerable plaques according to PROSPECT criteria

## **Study description**

### **Study objective**

Long-term mortality after vascular surgery in high-risk patients can be explained through atherothrombotic events and therefore be treated with adequate antithrombotic therapy.

### **Study design**

T=0: eligibility screening at outpatient clinic visit

T=1: CAG performance to evaluate cardiac risk

T=2a: Vascular Surgery

T=2b: Patient Randomization to study medication

T=3: 30 days after surgery -> first follow-up visit

T=5: 3 months after surgery -> second follow-up visit

T=8: 6 months after surgery -> third follow-up visit

T=11: 9 months after surgery -> fourth follow-up visit

T=14: 12 months after surgery -> fifth follow-up visit

End of study after 1 year of treatment.

### **Intervention**

Clopidogrel or placebo on top of standard treatment with aspirin

## **Contacts**

### **Public**

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### **Scientific**

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## **Eligibility criteria**

## Inclusion criteria

1. Preoperative myocardial injury (baseline value), defined as hsTnT release > 14 ng/L.
2. Absence of significant occlusive coronary artery disease as diagnosed through angiography (and confirmed by FFR).
3. Postoperative myocardial injury, defined as hsTnT release > 14 ng/L, which exceed the baseline value.

## Exclusion criteria

Potential subjects will be excluded with any of the following;

1. If event (i.e. hsTnT elevation) is diagnosed as myocardial infarction by cardiologist.
2. Presence of significant occlusive coronary artery disease, as diagnosed through preoperative angiography, requiring treatment.
3. No postoperative hsTnT values above the clinical reference of 14 ng/L and no rise with respect to baseline value.
4. Active bleeding.
5. Active cardiac conditions at the time of randomization such as unstable angina pectoris, active congestive heart failure (CHF), serious cardiac arrhythmias, symptomatic valvular disease.
6. Clear indication for long-term P2Y12 inhibitor use.
7. Preoperative use of P2Y12 inhibitors.
8. Previous allergy or intolerance to clopidogrel.
9. Use of oral anticoagulants after surgery.
10. Use of intravenous glycoprotein IIB/IIIA receptor inhibitors in the previous three days.
11. Coronary revascularization therapy in the previous six months.
12. Renal failure requiring dialysis.
13. Significant liver disease (i.e. ALAT, ASAT > 3x ULN).

- 14. Cancer with an expected life expectancy less than 6 months.
- 15. Excessive alcohol use.
- 16. No informed consent.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

### Recruitment

NL	
Recruitment status:	Suspended
Start date (anticipated):	01-07-2016
Enrollment:	100
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	06-07-2016
Application type:	First submission

## Study registrations

### Followed up by the following (possibly more current) registration

ID: 46172  
Bron: ToetsingOnline

Titel:

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

No registrations found.

## In other registers

Register	ID
NTR-new	NL5803
NTR-old	NTR5958
CCMO	NL54577.078.16
OMON	NL-OMON46172

## Study results