The Rotterdam Antiplatelet Therapy in Vascular Patients Study

Gepubliceerd: 06-07-2016 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28641

Bron
Nationaal Trial Register

Verkorte titel
RAVE

Aandoening

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.

Ondersteuning

Primaire sponsor: Erasmus Medical Center Rotterdam
Overige ondersteuning: Stichting Lijf en Leven

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

Clopidogrel or placebo on top of standard treatment with aspirin

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-07-2016
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-07-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 46172
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten