Platelet reactivity testing in association with perioperative microembolic signals during carotid endarterectomy.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Arteriosclerosis, stenosis, vascular insufficiency and necrosis
Study type	Observational invasive

Summary

ID

NL-OMON36721

Source
ToetsingOnline

Brief title
Platelet reactivity tests and MES during CEA

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
Carotid artery stenosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: carotid endarterectomy, microembolic signals, Platelet reactivity

Outcome measures

Primary outcome

Platelet reactivity (assessed by different tests: P-selectin FACS, VerifyNow,

PFA-100), Microembolic signals detected by transcranial doppler, and clinical

outcome.

Secondary outcome

Not applicable

Study description

Background summary

After a first manifestation of cardiovascular disease there is an increased risk for recurrence at the same or at another location in the vascular bed. Platelet inhibitors reduce cardiovascular events, but increase bleeding risk. Recent studies have showed significant platelet reactivity variability between patients taking platelet inhibitors and high platelet reactivity is associated with an increased risk of cardiovascular events. Monitoring platelet reactivity may be beneficial to reduce over and undertreatment and finally reduce thromboembolic and bleeding complications.
Currently, there is a wide range of tests which claim to measure platelet reactivity in different ways. Before platelet function tests can be used to determine the correct dose and type of platelet inhibitors in the vascular patient, further research is to be done. In the present study we asses platelet reactivity with thrombocyte P-selectine expression measurement, the VerifyNow system, and the PFA-100 system.
Nowadays tromboembolic and bleeding complications have a relatively low incidence and determining an association between the platelet function tests and complications would require very large studies. Micro embolic signals (MES) observed with transcranial Doppler (TCD) during carotid endarterectomy servers as a powerful surrogate marker for direct clinical validation of the platelet reactivity tests. This study will validate platelet reactivity tests with direct clinical thromboembolism registration to improve antiplatelet therapy in

patients with atherosclerotic disease.

Study objective

The primary aim of this study is to determine an association between the selected thrombocyte function tests and microembolic signals/clinical outcome. The test with the highest association will be the best strategy of assessing platelet reactivity in patients undergoing carotid endarterectomy. Furthermore we aim to identify the most important platelet activators in this setting. Our results will help selecting the optimal antiplatelet treatment for individual patients undergoing carotid endartectomy and will aid selecting antiplatelet therapy in other patients with cardiovascular disease.

Study design

Observational cohort study

Study burden and risks

Patients will be burdened with blood collection (45 ml total in 4 withdrawals) before and during surgery. Risks associated with blood collection are very small in the setting of carotid surgery.

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

Patients undergoing carotid endarterectomy

Exclusion criteria

Patients requiring a blood transfusion prior to surgery
Patients with an inappropriate temporal bone window for TCD
Patients on vitamin K antagonists
Patients with an artificial cardiac valve

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-07-2012
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO Date:	14-07-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-11-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL33061.041.10