Platelet reactivity over time in patients undergoing vascular surgery

Published: 26-07-2016
Last updated: 19-04-2024

The purpose of this study is to measure platelet reactivity at different time points in patients with platelet inhibitors. The primary research question in the intra-individual variety of platelet reactivity.

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

Summary

ID

NL-OMON46079

Source
ToetsingOnline

Brief title
Platelet reactivity testing over time

Condition

- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
antiplatelet therapy, atherosclerosis

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: Antiplatelet therapy, Platelet function testing, Vascular surgery

Outcome measures

Primary outcome

Platelet reactivity (measured by VerifyNow, VASP and PACT) at four different time points in patients undergoing carotid endarterectomy (CEA) and are treated with aspirin + P2Y12 inhibitor

Secondary outcome

Early thrombotic cardiovascular events (<2.5 months after surgery): cardiovascular death, transient ischemic attack, stroke, myocardial infarction, stent thrombosis, acute limb ischemia and the need for peripheral revascularization

Early bleeding complications (<2.5 months after surgery): secondary bleeding after surgery, gastrointestinal bleeding and brain hemorrhage.

Presence of a known CYP2C19 mutation

Quantification of platelet markers as (beta-thromboglobulin, platelet derived growth factor, RANTES and platelet- factor 4).

Study description

Background summary

After a first manifestation of vascular diseases, there is an increased risk of recurrence at the same site or at a different location of the vascular bed. Platelet inhibitors are prescribed in order to prevent these secondary cardiovascular events such as myocardial infarction, stroke or TIA. Although platelet inhibitors reduce the risk of a thrombotic event, the risk of bleeding increases. This indicates a narrow therapeutic range of platelet inhibitors.

Monitoring of the effectiveness of the platelet inhibitors may prevent under- and over-treatment, and thereby reduce the incidence of thrombotic or bleeding complications. Monitoring is done by different platelet reactivity test with varying sensitivity and specificity. At this time, there is no proven superiority of one of these tests.

The decision to proceed with a certain platelet inhibitor or to switch to a different medicament, is taken on the basis of a single platelet reactivity measurement. However, it is known that in healthy volunteers, without platelet inhibitors, there is a variability of platelet reactivy between different time intervals. A study which will studied platelet reactivity in patients on clopidogrel, observed a variation in platelet reactivity between the two time points. However, this study is of moderate quality, so there are no direct conclusions that can be drawn from this study.

Study objective

The purpose of this study is to measure platelet reactivity at different time points in patients with platelet inhibitors. The primary research question in the intra-individual variety of platelet reactivity.

Study design

Observational cohort study.

Study burden and risks

The burden for participant is low for the study. The subjects have to visit the hospital one time extra and undergo two extra venepunctures.
The burdens and risks of the venepunctures are low enough to justify participation of participants. Thereby, the treatment of a very large group of patients can be improved through this study.

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

-Taking antiplatelet therapy
- Undergoing elective carotid endarterectomy
- Admitted to the hospital at least 1 day postoperative
- older than 18 years

Exclusion criteria

- indication for postoperative Intensive Care opname
- are treated with vitamine K antagonists
- Need of per- or postoperative blood transfusion

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-12-2017
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	26-07-2016
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	14-09-2017
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	NL54610.041.15