Determination and/or following of High on-aspirin platelet reactivity (HARP) in CABG patients using the Verifynow Aspirin.

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Following the platelets aggregation inhibitory effect of aspirin pre- and post CABG, and the possible emergence of HAPR post CABG, measured with the VerifyNow Aspirin device.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON37275

Source
ToetsingOnline

Brief title
HAPR in CABG patients

Condition

- Coronary artery disorders

Synonym
Aspirin resitance, High on-aspirin platelet reactivity

Research involving
Human

Sponsors and support

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

Intervention

Keyword: CABG, HAPR, High on aspirin platelet reactivity, VerifyNow Aspirin

Outcome measures

Primary outcome

The primary endpoint is the moment that the number of 20 study subjects is

reached and there have been five measurements of ARU with each patient.

Secondary outcome

-Average of ARU's per moment of measurement.

-Difference in the ARU's per individual at different measuring moments.

-The time of first postoperatively Aspirin gift.

-Number of platelets at each measurement moment.

-Number and amount of any per-and postoperative platelet transfusions.

-Possible post-operative interventions (such as PCI, re-CABG, etc.) until the

measuring time T5.

Study description

Background summary

Aspirin is used for the prevention of thromboembolic occlusion of the grafts after a Coronary Artery Bypass Grafting after (CABG).
However multiple studies have shown that a significant part of the patients who use Aspirin are low- or non-responder for Aspirin. This means that these patients do not have the possible protective effect of aspirin on the grafts, causing a greater chance of graft occlusion. There are several devices that can measure the platelets aggregation inhibitory effect of aspirin and this can give a clue whether there is High on-aspirin platelet reactivity (HAPR) in the patients.
In this research is in 20 patients undergoing CABG looked at how they respond to Aspirin using one of these devices (VerifyNow Aspirin).
The VerifyNow Aspirin measure the platelet response on Aspirin, this is shown

in Aspirin Response Units (ARU's).
If the low- or non-responders can be identified, this may be a reason to replace Aspirin with another platelets aggregation inhibitory medium in these patients.

Study objective

Following the platelets aggregation inhibitory effect of aspirin pre- and post CABG, and the possible emergence of HAPR post CABG, measured with the VerifyNow Aspirin device.

Study design

It is a pilot for a clinical research involving 20 patients who are undergoing an elective CABG in UMC St Radboud,
These patients will be followed directly preoperative to six weeks postoperatively.
During this time, there are five different moments where the level of platelets inhibition is measured with the VerifyNow Aspirin and shown like the so-called Aspirin Raction Unitis (ARU's).

The five measurement moments are:
- Measurement 1 (T1): Direct preoperative on the operating room before the start of the operation.
- Measurement 2 (T2): on the operating room immediately postoperatively, after the end of the operation.
- Measurement 3 (T3): on the morning of the first postoperative day.
- Measurement 4 (T4): on the morning of the second postoperative day.
- Measurement 5 (T5): six weeks postoperatively on the postoperative policlinic.

On the above mentioned moments is blood collected that will be analyzed through the VerifyNow Aspirin.

At the moment the patients are included in the study (T0) and after the time that patients have been on the postoperative policlinic(T5) the following information is collected from the patient files and from the EPD:
-Number of platelets at each measurement.
-The time of first postoperatively Aspirin gift.
-Number and amount of any pre-, per- and postoperative platelet transfusions
-Postoperative blood loss.
-Comorbidities, relevance history or complications (e.g. CABG or PCI) and patient characteristics.

Study burden and risks

The burden and/or risks for participation in this research are insignificant.

Blood for the first 3 measurements is collected from intravenous or intra-arterial lines that the patient has around the operation. For the last 2 measurement the blood is collected trough a vein puncture.
In total there is about 15 ml more blood collected from the patient than the standard patient who is undergoing a CABG surgery at the UMC St Radboud. For the rest the study subjects has to answer a few questions at the postoperative policlinic regarding the medication use , therapy compliance and possible complications.

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

Elective pre-CABG patients (with during the CABG use of Heartlung machine)

Use of preoperative Aspirin

Exclusion criteria

Use of other platelets aggregation inhibiting medicines, NSAID'S, GPIIb/IIIa receptor antagonists, anticoagulants and/or heparines. (e.g., Dipyridamole, Acenocoumarol, Nadroparine, Plavix, etc.)
Under-age patients and minors.
Insufficient mastery of the Dutch or English to get wel informed.
Intolerance to aspirin.
Coagulation abnormalities, congenital platelets abnormalities and/or medication (non-aspirin) induced platelet abnormality

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):	07-01-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	27-09-2012
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL41667.091.12

Study results

Date completed:	09-06-2014
Actual enrolment:	21