Is Platelet Reactivity Measured with the VerifyNOw P2Y12 Platelet Function Assay Influenced by the Performance of a PCI Procedure and Procedural Characteristics - The POPular Process study

Published: 16-01-2014
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To determine whether platelet reactivity unit (PRU) values as assessed with the VerifyNow P2Y12 assay are influenced by the performance of a PCI procedure

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

Summary

ID

NL-OMON40557

Source
ToetsingOnline

Brief title
POPular Process

Condition

- Coronary artery disorders

Synonym
angioplasty, percutaneous coronary intervention

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: eigen financiering vanuit onderzoeksgroep

Intervention

Keyword: Clopidogrel, PCI, Platelet aggregation, Platelet reactivity

Outcome measures

Primary outcome

The primary endpoint is the difference in mean PRU value before and after the procedure in the arterial blood samples in patients treated with clopidogrel.

Secondary outcome

Secondary endpoint is the difference in mean PRU value before and after the procedure in the venous blood samples.

Secondary endpoint is the difference in mean PRU value between arterial and venous blood samples before and after the procedure.

Secondary endpoint is the difference in the rate of HPR before and after the procedure in arterial blood samples and in venous blood samples.

Secondary endpoint is the correlation between hematocrit and PRU values

Study description

Background summary

Dual antiplatelet therapy (DAPT) is essential in the treatment of patients

undergoing a percutaneous coronary intervention (PCI) to prevent atherothrombotic events such as stent thrombosis. However, in a substantial amount of patients receiving aspirin and clopidogrel the anticipated antiplatelet effect, as assessed with platelet function assays, is not optimally achieved. This state of so-called high platelet reactivity (HPR) observed in patients treated with these antiplatelet drugs is associated with a worse clinical outcome in patients who underwent PCI.
The occurrence of HPR is associated with many factors. The efficacy of the antiplatelet drug is influenced by clinical, pharmacologic and genetic factors, and some of those factors also have direct influence on platelet reactivity. The performance of the PCI procedure itself might also influence platelet reactivity. In fact, a study using the Multiplate platelet function test showed that platelet reactivity was elevated in patients after PCI. We want to investigate if platelet reactivity as assessed with the most frequently used platelet function test, the VerifyNow P2Y12 assay, is also influenced by performance of a PCI procedure.

Study objective

To determine whether platelet reactivity unit (PRU) values as assessed with the VerifyNow P2Y12 assay are influenced by the performance of a PCI procedure

Study design

Non-randomized, open label, single center study.

Study burden and risks

The patient will be informed about the study and written informed consent will be obtained before the patient enters the study. Blood samples will predominantly be obtained from vessels that are already punctured as part of routine care. As blood sampling though venipuncture is the only additional procedure, the study is not associated with any significant risks.

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

1. Scheduled for PCI
2. Adequately treated with clopidogrel (for the definition of adequate treatment see protocol page 9)

Exclusion criteria

1. Unable or unwilling to give informed consent
2. Presentation with ST-segment elevated myocardial infarction (STEMI)
3. Thrombolytic therapy within 24 hours before PCI or GPIIb/IIIa-inhibitors within the last 14 days
4. Laboratory results or diseases leading to unreliable VerifyNow results such as a known platelet count <100*10^9/L or coagulopathy or platelet disorder or a Haemoglobin < 6.5 or Hematocrit < 33%.

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):	28-01-2014
Enrollment:	115
Type:	Actual

Ethics review

Approved WMO Date:	16-01-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	02-07-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	08-09-2014
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL47163.100.13