intra-individual platelet activation, as meased by PFA-200, at different time lapses after aspirin intake

Published: 08-02-2013
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To eveluate the effect of amount of time past after last aspirin intake on platelet activability

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON39536

Source
ToetsingOnline

Brief title
Platelet activation in aspirin users, as measured by PFA-200

Condition

- Other condition
- Coagulopathies and bleeding diatheses (excl thrombocytopenic)

Synonym
Acute thromboembolic events

Health condition

Acute thrombo-embolische aandoeningen (cq. myocardinfarct, herseninfarct)

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: VUmc beheer B.V. 51072

Intervention

Keyword: Aspirin, PFA-200, Platelet activation

Outcome measures

Primary outcome

platelet activability as measured by PFA-200

Secondary outcome

platelet count

platelet activability as measured by chronolog

hemoglobone

Study description

Background summary

In search of an explanation and possible solution for aspirin resistance we postulate that when aspirin dosage interval is shortened, plateletactivability is reduced.

Study objective

To eveluate the effect of amount of time past after last aspirin intake on platelet activability

Study design

A cohort study, in which platelet activability, as measured by PFA-200 is evaluated in consideration with time past after last aspirin intake

Study burden and risks

A total of 84 ml of blood is withdrawn in 4 indivual wihdrawals. The risk seems

marginal. There are no benefits for individual patients.

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

Outpatients from the cardiology and vascular surgery departments. Intake of respectively 100 mg or 80 mg of carbasalate calcium or acetylsalicylic acid once a day.

Exclusion criteria

* active bleeding
* thrombocytopenia

* thrombocytosis
* recent use of antiplatet drugs, anticoagulants or drugs that are known to alter platelelet function, other than aspirin (e.g. NSAID*s, tirofiban, eptifibatide, abciximab, beta-lactam antibiotics, dextran, SSRI*s, clomipramine & amitriptyline, dipyridamole, verapamil, diltiazem , ginkgo biloba, ginseng, St John*s wort)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-07-2013
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	08-02-2013
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	31-05-2013
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-11-2013
Application type:	Amendment

Review commission: METC Amsterdam UMC

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	NL41763.029.12