Observing Platelet Activability in a Once daily vs. a More frequent Aspirin intake regimen

No registrations found.

Ethical review	Positive opinion
Status	Suspended
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21826

Source
NTR

Brief title
THE OPA & OMA-TRIAL

Health condition

Cardiovascular patients myocardial infarcation angina pectoris

Sponsors and support

Primary sponsor: VUmc, VU university medical center
Source(s) of monetary or material Support: Self-financing

Intervention

Outcome measures

Primary outcome

- PFA-200 parameters: closure time, flow slope, maximum rate of occlusion and area under the curve

- Chrono-log LTA parameters: Amplitude of aggregation given in percentages and the area under the curve.

- VerifyNow parameter: PRU

- TBX2 serum levels.

Secondary outcome

Platelet- , reticulated platelet- , leucocyte count and haemoglobin level

Study description

Background summary

Objective: Analyze whether a twice daily regimen is superior to a once daily regime of aspirin when it comes to inhibiting platelet aggregation in cardiovascular patients

Study design: Single blinded, open label, randomized cross-overy study.

Study population: 75 outpatients from the cardiology department, taking 80 mg of acetylsalicylic acid once a day. 10 healthy subjects will be used to define baselines in the assays that are being used.

Intervention: Study participants will sequentially be allocated to three dosage regimens, A1, B, and C. The order of allocation will be decided via randomisation. Regimen A and B are designed to establish a baseline activability of the platelets under a once a day regime of acetylsalicylic acid. In regimen C participants are put on a twice daily dosage regimen. NB circadian rhythm has been taken into account. .

Main study parameters/endpoints: We will analyze whether a twice daily regimen is superior to a once daily regime of aspirin when it comes to inhibiting platelet aggregation in cardiovascular patients, as measured by the PFA-200, Chrono-log light transmission aggregometry, VerifyNow, and a TBX2 serum ELISA.

Study objective

A twice daily intake regimen of aspirin provides a more stable inhibition within 24 hours after intake, compared to a once daily regimen.

Study design

Measured after 10 days of every intake regimen

Intervention

- Once daily intake regime 8.00 am, duration 10 days

- Once daily intake regime 8.00 pm, duration 10 days

- Twice daily intake regime 8.00 am & pm, duration 10 days

Contacts

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Eligibility criteria

Inclusion criteria

- Outpatients being treated for stable cardiovascular disease by the cardiology department.

- Stable cardiovascular disease defined as: coronary artery disease, peripheral vascular disease or previous myocardial infarction.

Exclusion criteria

- Active bleeding

- Diabetes mellitus

- Thrombocytopenia

- Thrombocytosis

- Thrombopathy (e.g. von Willebrand disease, Glanzmann’s thrombasthenia and Bernard–Soulier syndrome)

- Any ischemic event or revascularization procedure (percutaneous coronary intervention or coronary artery bypass grafting) within the last six months.

- Alcohol intake the day before blood sampling.

- Non-compliance to the protocol

- Recent use of antiplatelet drugs, anticoagulants or drugs that are known to alter platelet 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:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-06-2015
Enrollment:	85
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 24-03-2015
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 42162
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4976
NTR-old	NTR5114
CCMO	NL49455.029.14
OMON	NL-OMON42162

Study results

Summary results
https://www.tandfonline.com/doi/pdf/10.1080/09537104.2020.1809643