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

Gepubliceerd: 24-03-2015 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21826

Bron
NTR

Verkorte titel
THE OPA & OMA-TRIAL

Aandoening

Cardiovascular patients myocardial infarcation angina pectoris

Ondersteuning

Primaire sponsor: VUmc, VU university medical center
Overige ondersteuning: Self-financing

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Measured after 10 days of every intake regimen

Onderzoeksproduct en/of interventie

- 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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	01-06-2015
Aantal proefpersonen:	85
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	24-03-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 42162
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
https://www.tandfonline.com/doi/pdf/10.1080/09537104.2020.1809643