

Activity of platelets in patients recovering from severe infection

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Aspirin use as primary prevention in hospitalized patients recovering from pneumonia can inhibit platelet activity effectively. Also, we wonder if aspirin as secondary prevention in patients with stable cardiovascular disease works as effectively...

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

Samenvatting

ID

NL-OMON21579

Bron

Nationaal Trial Register

Verkorte titel

ASPIRIN-TRIAL

Aandoening

Infectious diseases

Ondersteuning

Primaire sponsor: Vrije Universiteit Medisch Centrum Amsterdam

Overige ondersteuning: Vrije Universiteit Medisch Centrum Amsterdam
Hartstichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Platelet aggregability, measured by:

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

- TBX2 serum levels

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Cardiovascular events can be triggered by a variety of common noncardiovascular clinical conditions, particularly those that are associated with systemic inflammation, such as a severe infection. Although the pathogenesis has not yet been clarified for 100%, hyperaggregability of thrombocytes seem to play a large part in the increased cardiovascular risk. Therefore this study will investigate the possibility of primary prevention by the use of aspirin in these high-risk patients with a severe infection. Objective: Measuring the efficacy aspirin to inhibit platelet activity in patients during (recovery from) a severe infection.

Study design: An open label randomized study will be conducted to measure platelet activity in patients during (recovery from) a severe infection and the efficacy of aspirin to inhibit platelet activity. Patients from the Internal & Pulmonary medicine ward will be screened for inclusion. Blood will be collected on three different days (24-72 hrs. after hospitalization, on day 14, and > 90 days after the first day of hospitalization) after the onset of the severe infection, once daily between 8.00-10.00 AM. This trial also comprises a substudy including 35 hospitalized patients with known cardiovascular disease diagnosed with pneumonia or invasive urinary tract infection or a cutaneous infection.

Study population: 97 (62 main trial and 35 sub-study) hospitalized patients with a severe infection.

Intervention (if applicable): Once daily aspirin vs. no aspirin. The sub-study is merely a observational study during which participants will be asked to standardize their aspirin intake to 1dd 8.00 AM intake.

Main study parameters/endpoints: PFA-200 parameters: closure time, flow slope, maximum rate of occlusion and area under the curve. Serum and plasma TxB2 levels. Platelet -, reticulated platelet-, leukocyte count and haemoglobin level will be measured to evaluate whether they are effect modifiers.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: There is minimal risk in this trial. Patient in the intervention group could benefit from the temporary protection of aspirin during a high risk period. Thus enduring a lower risk of acute cardiovascular events after the recovery from a severe infection.

Doel van het onderzoek

Aspirin use as primary prevention in hospitalized patients recovering from pneumonia can inhibit platelet activity effectively.

Also, we wonder if aspirin as secondary prevention in patients with stable cardiovascular disease works as effectively during an infection as when there is no infection

Onderzoeksopzet

- Day 1-4 since hospitalization (before intervention)
- Day 14 (after intervention)
- Day > 90

Onderzoeksproduct en/of interventie

Aspirin intake for 10 days

Group 1: no aspirin intake

Group 2: 80mg aspirin intake in the evening

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in the main-trial, a subject must meet all of the following

criteria:

Primary clinical diagnosis of pneumonia

OR

Primary clinical diagnosis of invasive urinary tract infection

OR

Primary clinical diagnosis of cutaneous infection

AND

18 years or older on the date of hospital presentation

AND

Hospitalization for at least 24 hours

AND

Having received at least 1 dose of antibiotics within 48 hours of admission.

In order to be eligible to participate in the sub-study, a subject must meet all of the following criteria:

Primary clinical diagnosis of pneumonia

OR

Primary clinical diagnosis of invasive urinary tract infection

OR

Primary clinical diagnosis of cutaneous infection

AND

18 years or older on the date of hospital presentation

AND

Hospitalization for at least 24 hours

AND

Having received at least 1 dose of antibiotics within 48 hours of admission

AND

Known stable cardiovascular disease. Stable cardiovascular disease defined as: coronary artery disease, peripheral vascular disease, or previous myocardial infarction (>12 months).

AND

Chronic usage of 80 mg of non-enteric coated acetylsalicylic acid once daily in the morning.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in the main-trial:

- Active metastatic cancer (c.q. malignancy)
- Allergy to salicylate
- Platelet count $<120 \times 10^9/l$
- History of non-traumatic major bleeding
- Known bleeding diathesis
- Conditions which require antiplatelet therapy

- Usage of antiplatelet therapy
- Surgery 1 month prior to diagnosis
- Currently pregnant
- Chronic usage of medication which are known to influence platelet function other than antibiotics (e.g. NSAID's, tirofiban, eptifibatide, abciximab, SSRI's, clomipramine, amitriptyline, dipyridamole, verapamil, diltiazem , ginkgo biloba, ginseng, & St John's wort)

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- Active metastatic cancer (c.q. malignancy)
- Platelet count $<120 \times 10^9/l$
- History of non-traumatic major bleeding
- Known bleeding diathesis
- Surgery 1 month prior to diagnosis
- Currently pregnant
- Cardiovascular event < 12 months prior
- Chronic usage of medication which are known to influence platelet function other than antibiotics or aspirin (e.g. NSAID's, tirofiban, eptifibatide, abciximab, SSRI's, clomipramine, amitriptyline, dipyridamole, verapamil, diltiazem , ginkgo biloba, ginseng, & St John's wort)

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland	
Status:	Werving gestopt
(Verwachte) startdatum:	01-10-2017
Aantal proefpersonen:	97
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum: 02-05-2017

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50157

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6251
NTR-old	NTR6425
CCMO	NL59727.029.16
OMON	NL-OMON50157

Resultaten