Activity of platelets in patients recovering from severe infection

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21579

Source
NTR

Brief title
ASPIRIN-TRIAL

Health condition

Infectious diseases

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum Amsterdam
Source(s) of monetary or material Support: Vrije Universiteit Medisch Centrum Amsterdam
Hartstichting

Intervention

Outcome measures

Primary outcome

Platelet aggregability, measured by:

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

curve)

- TBX2 serum levels

Secondary outcome

- Laboratory endpoints: platelet-, reticulared platelet-, leucocyte count, CRP, BSE, haemoglobin level

- Cardiovascular events

Study description

Background summary

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.

Study objective

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

Study design

- Day 1-4 since hospitalization (before intervention)

- Day 14 (after intervention)

- Day > 90

Intervention

Aspirin intake for 10 days

Group 1: no aspirin intake

Group 2: 80mg aspirin intake in the evening

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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*109/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)

A potential subject who meets any of the following criteria will be excluded from participation in the sub-study:
- Active metastatic cancer (c.q. malignancy)
- Platelet count <120*109/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)

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2017
Enrollment:	97
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	02-05-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 50157
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results