ASsesment of Platelet function and Inhibition in patients Recovering from severe INfection

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Main-trial:Measuring the efficacy of once daily aspirin to inhibit platelet activity in patients during (recovery from) pneumonia or invasive urinary tract infection or cutaneous infection.Sub-study:To assess the influence of an infectious state on...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON50157

Source
ToetsingOnline

Brief title
ASPIRIN-trial

Condition

- Coronary artery disorders

Synonym
Acute myocardial infarction, Heart attack

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Crowdfunding in samenwerking met de Hartstichting

Intervention

Keyword: AMI, aspirin, infection, prevention

Outcome measures

Primary outcome

PFA-200 parameters: closure time, flow slope, maximum rate of occlusion and

area under the curve

TBX2 serum levels.

Secondary outcome

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

possible effect modifying parameter.

Study description

Background summary

Cardiovascular events can be triggered by a variety of common non-cardiovascular clinical conditions, particularly those that are associated with systemic inflammation. 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 pneumonia or invasive urinary tract infection or cutaneous infection.Furthermore, we have added a sub-study, including patients with stable cardiovascular disease, to investigate whether a severe infection influence aspirin's efficacy to inhibit platelet activity in patients with know cardiovasular disease.

Study objective

Main-trial:
Measuring the efficacy of once daily aspirin to inhibit platelet activity in patients during (recovery from) pneumonia or invasive urinary tract infection or cutaneous infection.

Sub-study:

To assess the influence of an infectious state on aspirin*s efficacy to inhibit platelet activity in patients with stable cardiovascular disease.

Study design

An open label randomized study will be conducted to measure platelet activity in patients during (recovery from) pneumonia or invasive urinary tract infection of cutaneous infection and the efficacy aspirin to inhibit this platelet activity. Patients from the Internal & Pulmonary medicine ward will be screened for inclusion. Blood will be collected once dailty at fixed times at 8:00 AM. On three days : prior to randomization, on day 14 and > day 90.

Intervention

Main trial:
No treatment or 1dd 80mg aspirin. Repeated measurements of platelet function testing via venapuncture.

Sub-study:
No intervention, purely observetional. Repeated measurements of platelet function testing via venapuncture.

Study burden and risks

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 pneumonia or invasive urinary tract infection or cutaneous infection.

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

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
- 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 phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-01-2018
Enrollment:	97
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Ascal
Generic name:	Acetylsalicylic acid 80mg
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	27-03-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-04-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	02-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO Date:	20-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	17-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	25-05-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-09-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-10-2019
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

ID: 21579
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
EudraCT	EUCTR2016-004303-32-NL

Register	ID
CCMO	NL59727.029.16
OMON	NL-OMON21579