Trained platelets: Long term effects of Gram positive and Gram negative infections on platelet phenotype.

Published: 26-05-2016
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To study alteration in platelet function and RNA transcripts during and after a Gram positive and Gram negative infections.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON42945

Source
ToetsingOnline

Brief title
Trained platelets

Condition

- Bacterial infectious disorders

Synonym
bacteraemia, Sepsis

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Immunity, Long-term effects, Platelets, Sepsis

Outcome measures

Primary outcome

1) Platelet transcriptome during and after bacteraemia. 2) Platelet function

and platelet-leukocyte interaction

Secondary outcome

3) Platelet granule content (proteomics) 4) microparticle levels and phenotype

during disease.

Study description

Background summary

: Infectious diseases are associated with an increased risk for cardiovascular diseases (CVD). The mechanisms underlying this association are not fully elucidated. The risk for CVD following gram positive bacterial infections, such as caused by Streptococcus pneumonia or Staphylococcus aureus seems higher than during gram negative bacterial infections. Clinical studies have shown that the increased CVD for CVD also persists for a prolonged period of time.
Platelets are key cells in acute cardiovascular events but also in the progression of atherosclerosis. Platelets can recognize microbes and influence leukocyte function via a direct platelet-leukocyte interaction. Preliminary data from our laboratory showed that acute gram positive bacteremia is associated with more platelet activation and platelet-leukocyte interaction than gram negative bacteremia. How long these changes persist is unknown. The life span of a platelet is only 10 days, but infections may influence megakaryocytes. Platelets possess a wide array of RNA transcripts which can be altered during a wide array of diseases. The hypothesis that forms the basis of this study proposal is that a gram positive infection causes long term changes in platelet function and RNA transcript expression.

Study objective

To study alteration in platelet function and RNA transcripts during and after a

Gram positive and Gram negative infections.

Study design

A prospective observational study.

Study burden and risks

Participation in this study will not influence standard care. The study involves a maximum of one extra visit to the outpatient clinic and a maximum of three extra venipunctures. If possible the blood collection will be done during a venipuncture planned for regular care. There is a maximum of 159ml for the whole study procedure (6 weeks)

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

• >18 years
• Following infections:
o Positive blood culture pathogenic Gram positive bacteria (eg. Staphylococcus aureus (at least 10 with S. aureus), Streptococci)
o Positive blood culture with a pathogenic Gram negative bacteria (eg. E. coli (at least 10 with E. coli), K. pneumoniae)
• Expected duration of in-patient care of at least 3 days.
• Signed informed consent

Exclusion criteria

• Use of platelet function inhibitors (except aspirin)
• Antibiotic therapy for longer than 72 hours
• Myocardial infarction or stroke in the previous year
• An active hematologic or solid malignancy
• Terminal renal failure requiring dialysis
• Insulin dependent diabetes mellitus
• Solid organ transplant requiring anti-inflammatory medication
• Use of anti-inflammatory agents such as prednison (>7.5mg) or use of targeted biological agents (eg. TNF-blockers, monoclonal antibodies) with the exception of NSAIDs
• Micro-organisms that are well known contaminants in a blood culture (e.g. coagulase negative staphylococcus)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2016

Enrollment:	70
Type:	Actual

Ethics review

Approved WMO Date:	26-05-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL57239.091.16