The Immune Response during Sepsis in a Tropical setting; The impact of co-infection with HIV or malaria.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24875

Source
NTR

Brief title
ISIT

Health condition

sepsis, HIV, malaria

Sponsors and support

Primary sponsor: Tom van der Poll
Source(s) of monetary or material Support: Academic Medical Centre, Amsterdam

Intervention

Outcome measures

Primary outcome

Blood culture results, admission related mortality. In those with positive blood cultures: Sepsis related organ failure, systemic and cell specific markers of inflammation.

Secondary outcome

All cause mortality.

Study description

Background summary

Bacterial sepsis is a major cause of death in Africa. Recent evidence indicates that African patients with culture confirmed bloodstream infection are frequently co-infected with either HIV or malaria. Knowledge on the impact of these co-infections on the immune response during bacterial sepsis is highly limited. Therefore we will perform a prospective observational study to determine the impact of co-infection with HIV or malaria on the immune response during bacterial sepsis and its influence on clinical outcome. At the same time, we will identify micro-organisms causing sepsis and their antimicrobial resistance patterns. Patients will be recruited in the Albert Schweitzer hospital in Lambaréne, Gabon. We expect to enroll 2500 patients with symptoms indicating sepsis, of which an estimated 250 will have positive blood cultures. Cohorts (N = 50 per cohort) will be constituted consisting of patients with culture confirmed bacterial sepsis with or without co-infection with HIV or malaria, and afebrile controls without bacterial infection and with or without chronic HIV or malaria. In whole blood, plasma and purified blood cell populations, pro-inflammatory and anti-inflammatory markers known to be important in sepsis pathogenesis will be measured. In addition, gene expression profiles of purified cells will be compared using whole genome microarrays to discover new genes or pathways involved in sepsis pathogenesis.

Study objective

Co-infection with either HIV or malaria may have a major impact on the immune response during bacterial sepsis. Current knowledge on the pathogenesis of sepsis indicates an unbalanced response to infection characterized by both excessive pro-inflammatory responses and immune suppression. This disturbance is expected to be even more profound in the presence of HIV/malaria co-infection, at least in part due to hyper-responsiveness of PRRs triggering innate immunity.

Study design

Blood culture results: Maximum timepoint 7 days after admission.

Admission related mortality: Maximum timepoint 3 weeks after admission.

Sepsis related organ failure: Monitoring during admission.

Systemic markers of inflammation: Day 0, 2, 6 and 30.

Cell specific markers of inflammation: Day 2.

All cause mortality: 6 months.

Intervention

Venous blood draw.

Contacts

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Eligibility criteria

Inclusion criteria

1. Admission to Albert Schweitzer Hospital;

2. Age >17;

3. Temperature <36°C or >38° C;

4. One additional SIRS criterion (Heart rate >90bpm, Respiratory rate >20/min or leukocytes <4e9 g/L or >12e9 g/L).

Exclusion criteria

No informed consent.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-01-2011
Enrollment:	2500
Type:	Actual

Ethics review

Positive opinion

Date:	29-12-2011
Application type:	First submission

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
NTR-new	NL3071
NTR-old	NTR3219
Other	Scientific Review Committee of the MRU (Medical Research Unit) of the Albert Schweitzer Hospital : 2011.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A