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

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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-...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24875

Bron
NTR

Verkorte titel
ISIT

Aandoening

sepsis, HIV, malaria

Ondersteuning

Primaire sponsor: Tom van der Poll
Overige ondersteuning: Academic Medical Centre, Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

Venous blood draw.

Contactpersonen

Publiek

Centre of Experimental and Molecular Medicine
Meibergdreef 9, room F0-117
Mischa Huson
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5666378

Wetenschappelijk

Centre of Experimental and Molecular Medicine
Meibergdreef 9, room F0-117
Mischa Huson
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5666378

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

No informed consent.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	15-01-2011
Aantal proefpersonen:	2500
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	29-12-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A