Biomarker analysis in septic intensive care patients

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Ancillary infectious topics
Study type	Observational invasive

Summary

ID

NL-OMON36605

Source
ToetsingOnline

Brief title
The BASIC-study

Condition

- Ancillary infectious topics

Synonym
blood poisoning, Sepsis

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Center for Translational Molecular Medicine (CTMM)

Intervention

Keyword: Biomarker, Inflammation, Prognosis, Sepsis

Outcome measures

Primary outcome

90-day mortality

Secondary outcome

-Multi organ dysfunction syndrome (MODS) according to Marshall criteria

increasing abnormalities in the following organ specific parameters:

PO2/FiO2 ratio (lung)

Serum creatinine (kidney)

Platelet count (clotting system)

Glasgow coma score (neurological)

Serum bilirubin (hepatic)

Pressure-adjusted heart rate (HR): (HR x (Central Venous Pressure/Mean

Arterial Pressure)) (heart)

-Etiology (bacterial and/or viral)

-CRP,CRP-complement complex

-Parameters of systemic inflammation (cytokines, chemokines, complement

activation, cell numbers and differentiates)

-Parameters of local inflammation (cytokines, chemokines, complement

activation, cell numbers and differentiates)

-Coagulation/fibrinolysis parameters (both systemic and local)

-Markers for cellular damage

-Demographic data, medical history and health condition prior to

hospitalization will be documented for all patients.

Study description

Background summary

Sepsis is a common entitiy on the intensive care and is an often lethal disease. Sepsis is a disorder in which a pathogen triggers an systemic inflammatory respons. During a septic episode a disproportionate immuneresponse occurs in the patient possibly leading to dysfunction of multiple organs (multi organ dysfunction syndrome (MODS)). In many cases the pulmonary compartment is targeted by the host's own immunesystem resulting in acute lung injury (ALI) or acute respiratory distress syndrome (ARDS). Investigating sepsis is extremely difficult due to the heterogenous character of sepsis with it's multiplcity in etiology and the complex immunesystem responding as effector. In this study we try by means of a multi-approach strategy to gain more insight in the pathophysiologic proces of sepsis.

Study objective

The aim of this study is to create a prognostic model enabling the clinician to predict the outcome of a septic episode. Furthermore, by getting more insight in the pathophysiologic proces of sepsis, we could discover new possible targets for future therapeutic interventions.

Study design

A longitudinal study in which 1067 septic, 500 non-infectious SIRS patients and 500 healthy age, gender and chronic co morbidity matched volunteers are included. The patients are on the ICU of the Academic Medical Centre in Amsterdam (AMC). In the septic patients blood will be collected three times a day for seven consecutive days to analyse the patients systemic immune status. Furthermore, a non-directed broncho-alveolar lavage will be performed in mechanically ventilated patients on day 1, 2, 4 and 7 to determine the immunestatus of the pulmonary compartment. Also, a nose-/throat swab will be performed on day 1 and 4 for viral diagnostics.

In the SIRS group the same diagnostics are performed, but only once a day.

The healthy control group will be subjected to a single blood draw of 12ml.

Study burden and risks

Patients will experience a minimal burden by participating in this study. Blood required for analysis will be collected through an already placed arterial line. The non-directed broncho-alveolar lavages in this study are seen as a standardisation of routine handlings of patient care.

Patients are not subjected to any additional risks by participating in this study.

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

Age: 18 years and older
Presence of an arterial line;Sepsis group: Patients admitted to the intensive care with sepsis, or patients developing sepsis during their stay on the intensive care.;SIRS patients: Critically ill patients who score positive on at least two SIRS criteria who do not suffer from sepsis and have an expected ICU stay of more than 24 hours.;Healthy volunteers: All healthy individuals without any recent febrile or infectious illness (within 2 weeks). Individuals capable of giving written informed consent.

Exclusion criteria

No informed consent;Patients receiving more than 24 hours of antibiotic treatment for a suspected infection prior to ICU admission.;Sepsis group: Previous participation in this study.;SIRS group: Previous participation in this study.;Healthy volunteers: Previous participation in this study.
A major illness in the past 3 months or any significant chronic medical illness that the investigator would deem unfavorable for enrolment, including inflammatory diseases.
A recent febrile illness (within 2 weeks).
Recent use of anti-inflammatory medication (within 2 weeks).
Subject using tobacco and/or illicit drug products.
Current use of hormone therapy or current pregnancy.
Limited accessibility of a vein in the left or right arm.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-04-2011
Enrollment:	2067

Type:	Actual

Ethics review

Approved WMO Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL34294.018.10