Biomarkers of Sepsis

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In this study we aim to develop a predictive model for septic ICU*patients enabling the clinician to make a customized risk stratification and asses the patient*s immune status.

Ethical review	Not approved
Status	Will not start
Health condition type	Ancillary infectious topics
Study type	Observational invasive

Summary

ID

NL-OMON36119

Source
ToetsingOnline

Brief title
Biomarkers of Sepsis

Condition

- Ancillary infectious topics

Synonym
blood poisoning, sepsis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Center for Translational Molecular Medicine (CTMM)

Intervention

Keyword: biomarkers, intensive care unit, predictive model, sepsis

Outcome measures

Primary outcome

Mortality is the primary study endpoint.

Secondary outcome

Secondary endpoints include pathogen etiology, systemic inflammatory parameters and MODS. The secondary endpoints will enable us to develop a predictive model for risk stratification for sepsis and provides insight in the pathophysiologic processes of sepsis and might lead to novel therapeutic interventions.

Study description

Background summary

Sepsis is a common clinical entity in Intensive Care Unit (ICU)*patients. Despite many years of research, sepsis is still the second leading cause of death in these patients. Sepsis occurs as a complication of a local infection when microorganisms invade the host*s bloodstream and cause systemic inflammation. The systemic response to pathogens can lead to a disproportionate activation of pro* and anti*inflammatory mediators, resulting in a state of hyperinflammation. This exaggerated immune response can induce organ dysfunction and results in the multi organ dysfunction syndrome (MODS). Through the years, investigating the pathophysiology of sepsis has proven to be extremely difficult due to the heterogeneous character of this disease with its multiplicity in etiology and the complex immune system as effector.

Study objective

In this study we aim to develop a predictive model for septic ICU*patients enabling the clinician to make a customized risk stratification and asses the patient*s immune status.

Study design

This is a longitudinal observational study.

Study burden and risks

All patients are subjected to collection of blood samples 3 times a day for 7 consecutive days.
Patients will not directly benefit from participating in this study due to it*s observational design. Future patients with sepsis, however, could benefit of the outcome of this study. During this study participating patients will not be exposed to any additional health risks.
During this study, patients will be subjected to a daily blood draw of 13.5 ml per day. Considering this is a mere 0.2 percent of the total circulating volume, this will not attribute to any of the patients burdens, nor result in an additional risk.

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
- Presence of an arterial line
- Patients who score positive for sepsis according to the Bone criteria (at least 2 SIRS criteria plus clinical suspicion of infection).

Exclusion criteria

- No informed consent.
- Patients receiving > 24 hours of antibiotic treatment for a suspected infection prior to ICU admission.
- Previous participation in this study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	500
Type:	Anticipated

Ethics review

Not approved

Date:	28-03-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL35777.041.11