Neutrophil dysfunction and sepsis in ICU patients.

Published: 12-12-2006
Last updated: 10-08-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON31712

Source
ToetsingOnline

Brief title
NERTHUS-Study II

Condition

- Other condition
- Immune disorders NEC
- Bacterial infectious disorders

Synonym
multiple organ failure, Sepsis

Health condition

Trauma en acute post-operatieve patiënten

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Critically ill patients, Neutrophils, Recirculation, Sepsis

Outcome measures

Primary outcome

Primary variables:

- Degree of inactivity of neutrophils

Primary outcome:

- Development of inflammatory-induced complications (sepsis/septic shock/(multiple) organ failure)

(According to the SIRS/Sepsis criteria)

Secondary outcome

Secundary variables:

- Normalization of neutrophil receptor profile
- Percentage of cells in specific populations of neutrophils.

Secundary outcome:

- Development of inflammatory-induced complications (sepsis/septic shock/(multiple) organ failure)
- Severity of illness during the intensive care period

(According to disease severity on admission: APACHE II Score)

(According to the maximal SOFA score during admission)

Study description

Background summary

Multiple organ failure due to the presence of sepsis is an important cause of death in intensive care patients. Neutrophils play an important role in the defence mechanisms against bacteria. Dysfunction of this component of the innate immune system can lead to a paralysis of the immune system, which can lead to sepsis. How this dysfunction of neutrophils develops and in which timeframe is unknown.

Study objective

In previous studies we have identified specific receptor and surface protein expression profiles on neutrophils. Some of these profiles point at partially refractory neutrophils.
In the current NERTHUS study we have seen that circulating neutrophils are less responsive to inflammatory stimuli. During the first 12 hours after injury, the responsiveness of neutrophils is considerably lower in patients developping septic complications compared to those who do not.
The aim of this study is to validate the correlation between neutrophil unresponsiveness and the development of inflammatory-induced complications.

Study design

Immediately after admission (within 16 hours) a blood sample is taken. Thereafter, bloodsamples will be taken on day 5 and 6 of admission. The blood will be analyzed on the presence of neutrophils. These neutrophils are analyzed for their degree of activation and the presence of specific surface proteins.
The APACHE II Score is determined on admission. Furthermore, the SOFA score and MODS score are calculated on a daily basis. This can be done by variables which are determined daily on the intensive care.
The presence of sepsis is classified by the SIRS/Sepsis criteria.

Study burden and risks

There is no additional risks involved for the patient. The blood taken on a daily basis is drawn from the arterial line. The study protocol stops when the patient leaves the intensive care.

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

1) Patients admitted to the intensive care unit
2) After sugery or major trauma
3) Age above 18
4) Expected stay > 2 days

Exclusion criteria

Immunological compromised - e.g. patients treated with steroids and/or cytostatic drugs

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):	12-03-2007
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO Date:	12-12-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	11-11-2008
Application type:	Amendment
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	NL11380.041.06