A pilotstudy to clinical scorings systems and biomarkers in blood and urine of sepsis patients in the emergency care

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

Summary

ID

NL-OMON37120

Source
ToetsingOnline

Brief title
Predicting sepsis in the emergency care: A pilot study

Condition

- Other condition

Synonym
blood poisoning, Sepsis

Health condition

Sepsis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: MODS, Sepsis, SIRS

Outcome measures

Primary outcome

Main endpoints are mortality and clinical course of the admission.

Secondary outcome

Secondary endpoint will be the development of acute kidney injury.

Study description

Background summary

Sepsis is a life-threatening condition with a mortality rate of 30-70%. Most deaths are the result of multi organ failure due to systemic inflammation. Considering the high mortality rate, it is essential to distinguish patients that will develop severe sepsis and thus need aggressive therapy and ICU admission. Several instruments for predicting sepsis severity have been developed, however not many studies have compared different instruments and therefore evidence for which instrument works best is lacking. Evaluating biomarkers in blood and urine is a possible way to predict multi organ failure in sepsis and thereby the need for aggressive therapy, but for which biomarker is best, evidence is also lacking . In this pilot study we will compare three simple sepsis severity prediction instruments and several biomarkers in blood and urine for their ability to predict the sepsis severity in the emergency department of the UMCG. We will also evaluate the predictive value of the instruments for intensive care unit admission.
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Study objective

The aim of this study is to determine which predictive instrument is most reliable in predicting sepsis severity in de emergency department: the SIRS criteria, the PIRO score or the clinical impression scale. Furthermore, we want

to determine whether a correlation exists between several biomarkers in blood and urine and sepsis severity.

Study design

A prospective, observational pilot study with 160 patients having (suspected) sepsis in the emergency department.

Intervention

Scores derived from clinical impression score and PIRO sepsis staging score, SIRS criteria, and relevant biomarkers in blood and urine at arrival at the emergency department will be compared to clinical development, intensive care unit admission, mechanical ventilation necessity, development of acute kidney injury and mortality.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: blood and urine samples will be collected at the emergency department. The doctor and nurse will report their clinical impression score. The SIRS criteria and PIRO sepsis staging score will be calculated from laboratory findings and the medical record. The burden for subjects is minimal. In case of suspected sepsis, blood and urine samples are routinely collected and no additional vena punction has to be performed.
The subjects will be recruited from a group of patients who will be partially unable to give informed consent due to their condition at the moment of admission at the emergency department. Especially subjects suffering from septic shock may have altered consciousness. Informed consent will always be obtained before enrolment in the pilot study, either from the patient or from a person with the legal right to represent the patient.
The subjects will receive the same therapy as patients who do not participate in the study. Subjects may benefit from participating in the study, because the severity of their condition may be recognized earlier, something researchers have proved to be of great importance for the prognosis of septic patients

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 year
Patients with suspected infection and two or more of the SIRS criteria [temperature <36*C or >38*C, heart rate > 90 beats/minute, respiratory rate >20 per minute, WBC > 12.000 or < 4000 cells/micro liter or pCO2 < 4.2 kPa] in the emergency department, who will be admitted to a ward or intensive care unit.
Informed consent.

Exclusion criteria

Age <18 years, not admitted from the Emergency Care.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-07-2012
Enrollment:	160
Type:	Actual

Ethics review

Approved WMO

Date:	08-08-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL40532.042.12