Identifying new biomarkers for sepsis diagnosis with proteomics techniques

Published: 01-07-2008
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To identify new blood based protein biomarkers for the diagnosis of sepsis.

Ethical review	Not approved
Status	Will not start
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON32062

Source
ToetsingOnline

Brief title
Sepsis study

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
infection, sepsis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Pronota

Intervention

Keyword: biomarkers, diagnosis, proteomics, sepsis

Outcome measures

Primary outcome

The main endpoint is a list of potential biomarkers differentiating patients

with sepsis and patients with SIRS (diagnostic).

Secondary outcome

Not applicable.

Study description

Background summary

Sepsis may be difficult to diagnose and a delay in diagnosis can be fatal. The mortality of severe sepsis/septic shock ranges from 30% to 70%. Despite all the research on sepsis, good biomarkers are unavailable.
The discipline of proteomics can potentially identify new biomarkers for sepsis.

Study objective

To identify new blood based protein biomarkers for the diagnosis of sepsis.

Study design

An extra vial (10 ml blood) will be taken during the study: Prestudy Optimizing Diagnosis of Community-Acquired Pneumonia (CAP study), during routine sampling and blood sampling for the CAP study. Within 24-48 hours after admission, informed consent will be asked to use these materials for diagnostic esearch.
If no consent is given, the materials will be destroyed.
When informed consent is given for participation in the study, the materials will be analysed with proteomics techniques.

Study burden and risks

Burden: 10 ml extra blood is taken
Risks: no extra risks

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) Admission with suspected Community Acquired Pneumonia
2) Age: adult (18 years and older)
3) SIRS criteria
4) Informed consent

Exclusion criteria

1. Recent admission (<2 weeks), or living in nursing home
2. History of bronchial obstruction or postobstruction pneumonia. Patients with COPD will not be excluded.
3. History of lungcancer or pulmonary metastases

4. AIDS, known or suspected pneumonia caused by Pneumocystis Carinii or known or suspected active tuberculosis.
5. unability to give informed consent

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	15
Type:	Anticipated

Ethics review

Not approved

Date:	01-07-2008
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	NL23746.041.08