Tissue oxygenation in severe sepsis.

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Objectives: 1) Describe the course of muscle SrO2 in patients with severe sepsis in relation to outcome and severity of disease 2) Describe the relationship between muscle SrO2 and serum lactate, SvO2, DO2 and VO23) Describe the course of cerebral...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON34452

Source
ToetsingOnline

Brief title
TOSS studie.

Condition

- Bacterial infectious disorders

Synonym
Severe sepsis/ delirium

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Delirum, INVOS, Oxygenation, Severe sepsis

Outcome measures

Primary outcome

Main study parameters/endpoints: Primary endpoints will be delirium and the correlation between SrO2 and SvO2.

Secondary outcome

Secondary endpoints will be duration of reversal of sepsis, mortality, duration of ICU stay, duration of hospital admittance and duration of mechanical ventilation.

Study description

Background summary

The true endpoint of resuscitation in intensive care medicine is maintenance of aerobic circulation. This almost philosophical goal is hard to measure. So far, measurement of local perfusion by infrared camera is as close as one can get, but measurement of tissue oxygenation is the next step. This protocol describes the possibilities of testing the measurement of tissue oxygenation in muscle and brain in patients with severe sepsis.

Study objective

Objectives:
1) Describe the course of muscle SrO2 in patients with severe sepsis in relation to outcome and severity of disease
2) Describe the relationship between muscle SrO2 and serum lactate, SvO2, DO2 and VO2
3) Describe the course of cerebral SrO2 during the course of severe sepsis
4) Describe the relationship between cerebral SrO2 in patients with severe sepsis and delirium

Study design

Study design: An observational single center pilot study.

Study burden and risks

The only burden for the participant consists of 2 electrodes being placed on the head and 1 on the arm. The only theoretical risk is an allergic reaction to the INVOS electrode. There is no clear benefit for the included patients of 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
severe sepsis(2 SIRS criteria plus focus of infection) and organ failure
written informed consent
Picco guided resuscitation

Exclusion criteria

Terminal phase of disease

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-10-2010
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	24-08-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL32009.100.10
Other	NL32009.100.10