"Early detection of sepsis : a randomized clinical trial."

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29428

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Surviving Sepsis Campaign, sepsis guidelines, Early Goal Directed Therapy, severe sepsis and septic shock, screening for sepsis.

Sponsors and support

Primary sponsor: none
Source(s) of monetary or material Support: none

Intervention

Outcome measures

Primary outcome

Differences in time of detection of possible sepsis, differences in time of the first lactate level-test and differences in time of the first resuscitation bundle were registered in both groups.

Secondary outcome

Number of septic patients in both groups.
Duration of inotropic therapy (hours) in both groups.

Duration of mechanical ventilation (hours) in both groups.

Study description

Background summary

Evidence suggests that early recognition and time-sensitive resuscitation for patients with severe sepsis and septic shock can significantly improve their outcome. To obtain this objective Protocol Watch was developed as an early warning score system. The purpose of this research was to measure the benefit of the application of this bedside tool in comparison with the standard observation and interpretation of the critical team.

Study objective

“Can the use of the Protocol Watch improve the earlier detection of sepsis?”
The hypothesis is that the use of the Protocol Watch improves the earlier detection of sepsis with at least 60 minutes.

Study design

T 1 --> Differences/delays in time zero of the identification will be compared in both groups. Time zero is set on the moment of detection of possible sepsis (= 2 positive sirs criteria + infection).

T 2 --> Differences/delays in time zero of the first lactate level-test will be compared in both groups.

T 3 --> Differences/delays in time zero of the resuscitation will be compared in both groups. Time zero here is set on the start of the first sepsis bundle, namely the first gift of antibiotics after retrieving blood cultures and the simultaneously start of the fluid resuscitation.

Intervention

The Protocol watch (PW), designed by Philips Healthcare is a new clinical support application on the patient monitor that assists clinicians in the implementation of the SSC guidelines. Protocol watch monitors the patients for the signs and symptoms of sepsis and notifies you when SIRS/Sepsis conditions occur.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients admitted between Januari 1, 2009 - March 1, 2010;

2. Adult patients admitted on the surgical intensive care unit (at least 18 years of age);

3. Patients receiving major thoracic, vascular, neuro, abdominal and urologic surgery;

4. Polytraumapatients.

Exclusion criteria

1. Patients admitted on the SICU with sepsis;

2. Expected length of SICU stay less than 48 hours.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2009
Enrollment:	450
Type:	Anticipated

Ethics review

Positive opinion

Date:	13-12-2008
Application type:	First submission

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
NTR-new	NL1518
NTR-old	NTR1587
Other	METC : 08.52/08.01
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A