Comparison of SIRS criteria and qSOFA score for identifying sepsis in the Emergency Department

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23850

Source
NTR

Brief title
TBA

Health condition

sepsis

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

The aim of our study is to compare the diagnostic accuracy of SIRS criteria and qSOFA score in identifying sepsis in undifferentiated patients at the ED. to investigate the predictive value regarding patient outcomes like in-hospital mortality and ICU admission.

Secondary outcome

The predictive value regarding patient outcomes like in-hospital mortality and ICU admission.

Study description

Background summary

OBJECTIVE: Sepsis is a major cause of death amongst critically ill patients worldwide. Currently, both SIRS criteria and/or qSOFA score are used for identifying sepsis without a uniform standard. The aim of this study is to compare the accuracy of SIRS criteria and qSOFA score by identifying sepsis in undifferentiated patients in the Emergency Department (ED).
DESIGN: A cross-sectional multicenter study.
SETTING: EDs at two European clinical teaching hospitals in the Netherlands.
PARTICIPANTS: In total, 750 adult patients with suspected infection who meet SIRS criteria or have a qualifying qSOFA score who were treated at two EDs in the Netherlands from 1st January 2018 until 1st March 2018 were included.
METHODS: SIRS criteria and qSOFA score were calculated for each patient. The first hospital treated patients who met SIRS criteria following their standardised hospital protocol for sepsis. At the second hospital, only patients who met the qualifying qSOFA score received this treatment. Because of this, patients could be divided into five groups (1: SIRS+, qSOFA-, not treated according protocol (reference group); 2: SIRS+, qSOFA-, treated according protocol; 3: SIRS+, qSOFA+, treated according protocol; 4: SIRS-, qSOFA+, not treated according protocol; 5: SIRS-, qSOFA+, treated according protocol). Patients could be treated outside the protocol when the treating physician considered it necessary.
PRIMARY AND SECONDARY OUTCOME MEASURES: To prove infection was present, positive cultures were used as the primary outcome. Secondary outcomes were in-hospital mortality and ICU admission.

Study objective

There is no difference between the diagnostic accuracy of SIRS criteria and qSOFA score in identifying sepsis in undifferentiated patients at the ED.

Study design

2019-01 data extraction by student
2020-01 analyse
2020-06 writing paper

Intervention

none

Contacts

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Eligibility criteria

Inclusion criteria

* patients aged 18 years and older visiting the ED in Amphia Hospital, Breda or the ED in Maxima Medical Hospital, Veldhoven between 2018-01-01 and 2018-03-03
* ≥2 of the SIRS criteria or ≥2 of the qSOFA score who visited the ED with a suspected infection or sepsis
* were triaged at level U1, U2 or U3 by the NTS
* visited the ED for internal, pulmonary, gastrointestinal or urology medicine

Exclusion criteria

* patients aged under 18 years old

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2020
Enrollment:	750
Type:	Actual

IPD sharing statement

Plan to share IPD: Yes

Plan description
The inclusion of patients was conducted by one medical student at Máxima MC and three residents and one medical student at Amphia Hospital. Data collection started at Máxima MC and was supplemented at Amphia Hospital until 750 patients were achieved and the patient-input from both hospitals came balanced. Data collection at Amphia Hospital stopped halfway through February 2018 due to staff occupation, but this did not affect the power of this study. Data were obtained manually from the electronic hospital records using structured electronic data collection forms. All data were de-identified and stored in a secure data management system.

Ethics review

Positive opinion

Date:	16-01-2020
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	NL8315
Other	METC Maxima MC : N17.180

Study results