Trial Description

Title

Evaluation of clinical validity of the quickSOFA Score in early recognition of sepsis

Trial Acronym

SEED (SEpsis in Emergency Department)

URL of the trial

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Brief Summary in Lay Language

Sepsis is a life-threatening organ dysfunction and the most severe form of an infection. In Germany, approximately 150 000 people suffer from sepsis every year; the lethality is around 30%-50 %. A quick recognition and an appropriate treatment determine the prognosis as sepsis is often underdiagnosed. In early 2014 a task force made of critical care, infectious disease, surgical and pulmonary specialists, convened to develop a new, simple and quick score for an early diagnosis of patients with suspected infection. It's called quick SOFA (qSOFA). This measure contains three criteria: a respiratory rate of 22/min and greater (1 point), a systolic blood pressure of 100mmHg or less (1 point) and an altered mentation (1 point). One point is assigned for each clinical variable. If there are two or three points out of three, a sepsis is likely and requests medical activities. At the moment, the qSOFA Score is not part of the daily standard practise at the emergency department Freiburg because there is insufficient evidence to show if qSOFA is really a reliable working tool.
Structure of the study: The study performs in the emergency department Freiburg. Every emergency patient, triaged to an emergency severity index 1, 2 or 3 , will be screened with the qSOFA Score. This screening contains vital signs like respiratory rate, blood pressure and Glasgow coma scale. To find a correlation between the qSOFA Score and the clinical outcome, there will be a research with the internal database of the patient history after the hospital stay including medical treatment and laboratory findings.
The purpose of this study is to clarify, whether patients at high risk of developing sepsis can be detected effectively with the qSOFA and could therefore benefit from a quick diagnostic and initiation of therapy

Brief Summary in Scientific Language

In early 2016, the "third international consensus definitions for sepsis and septic shock" introduced a new bedside score, called quick SOFA (qSOFA) to help identify patients with sepsis or patients at high risk of developing sepsis , as early recognition and effective treatment of sepsis improve the outcome of these patients. The task force validated the criteria for qSOFA Score based on the results of large retrospective data using the three most significant parameters of the detailed SOFA Score (Sequential Organ Failure Assessment). The qSOFA Score ranges from zero to three points, with one point for each parameter: respiratory rate 22 /min or greater (1 point), systolic blood pressure of 100mmHg or less (1

point) and alerted mental status, equal to a Glasgow coma scale (GCS) of 14 or less (1 point). The task force strongly recommended international validation in different study settings. Currently there is no standard qSOFA screening in the emergency department Freiburg because it is still unclear if the score is a reliable instrument for measuring the risk of sepsis.
The purpose of this study is to assess the validity of the qSOFA scoring system in an emergency department and to evaluate its screening capacity. To find a correlation between the qSOFA Score and the clinical outcome, there will be a retrospective research of the patient history during the hospital stay, after the prospective data survey in the emergency department.

Inclusion criteria:
-Hospital treatment during investigation period
-Assign to team internal medicine, neurology, urology, visceral surgery
-Assign to Emergency Severity Index (ESI) category 1, 2 or 3
-Time since patient-intake in emergency department < 60min
-Patient age > 18 years

Exclusion criteria:
-Assign to team trauma surgery or plastic surgery
-Assign to Emergency Severity Index (ESI) category 4 or 5
-Time since patient-intake in emergency department >60min
-Patient age <18 years
-Intubated / mechanically ventilated patients
-hospital- acquired sepsis

Organizational Data

- DRKS-ID: **DRKS00012732**
- Date of Registration in DRKS: **2017/07/17**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **330/17 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **A41 - Other sepsis**
- ICD10: **R57.2 - Septic shock**

Interventions/Observational Groups

- Arm 1: **All emergency patients (ESI (Emergency Severity Index) 1-3, for details see exceptions exclusion criteria) are screened for qSOFA Score (respiratory rate rate, blood pressure and mental status) in the emergency department Freiburg. Afterwards there will be a retrospective research of the patient history during the hospital stay, including medical treatment and laboratory findings.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Diagnostic**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

- Sepsis- yes or no. Identification with discharge diagnosis (retrospective)
- qSOFA Score should be measured once within the first 60 mins after triage. This measure contains three criteria: respiratory rate, blood pressure and an altered mentation

Secondary Outcome

Outcome: mortality, transfer in hospital, stay at intensive care unit, medical treatment (start antibiotics), effect concomitant diseases, laboratory findings (data collection retrospective)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/07/19**
- Target Sample Size: **2500**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- Treatment in Universitäts-Notfallzentrum in Freiburg during investigation period
- Assign to team internal medicine, neurology, urology, visceral surgery
- Assign to Emergency Severity Index (ESI) category 1, 2 or 3
- Time since patient-intake in emergency department < 60min
- Patient age > 18 years

Exclusion criteria

- Assign to team trauma surgery or plastic surgery
- Assign to Emergency Severity Index (ESI) category 4 or 5
- Time since patient-intake in emergency department >60min
- Patient age <18 years
- Intubated / mechanically ventilated patients
- hospital- acquired sepsis

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*