PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Effects of procalcitonin-guided antimicrobial stewardship on reduction of antibiotical use in patients with severe sepsis or septic shock: a retrospective analysis.

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Severe infection in Critical Care environment still remains a serious complication with high morbidity and mortality. An early start of antibiotic treatment has be convincingly shown to reduce mortality in critical ill patients. The development of antibiotic resistances of bacterial species, due to antibiotic overtreatment, has rendered indications and administration of available antibiotic substances as subject of reconsideration and discussion.
As a consequence of that, we implemented a Procalcitonin (laboratory marker for bacterial infection) guided algorithm.
This retrospective study analyse the effect of this program on antibiotic use in patients with severe life-threatening infection.

Brief Summary in Scientific Language

Sepsis in ICU still remains a serious complication with high morbidity and mortality and considerably adds to health care expenses in intensive care medicine. An early start of antibiotic treatment has been convincingly shown to reduce mortality in critically ill patients. The development of antibiotic resistances of bacterial species, due to antibiotic overtreatment, has rendered indications and administration of available antibiotic substances as subject of reconsideration and discussion.
As a consequence of that, we implemented a procalcitonin (PCT)-algorithm to guide antibiotic treatment in severe infections which are know to be effective to reduce antibiotic use. This retrospective study analyses the effects of this program in clinical practice on antibiotical use in patients with severe sepsis and septic shock. Primary outcome parameters were: Lenght of ICU-Stay, 28-day mortality, Ventilation hours, Days on antibiotic therapy, ICU re-infection rate and mean antibiotic costs (per patient).

Organizational Data

- DRKS-ID: **DRKS00003490**
- Date of Registration in DRKS: **2012/02/08**
- 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.: **D 409/10 , Ethikkommission der Christian-Albrechts-Universität zu Kiel**

Secondary IDs

Health condition or Problem studied

- ICD10: **A41.9 - Septicaemia, unspecified**
- ICD10: **R57.2 - [generalization R57: Shock, not elsewhere classified]**

Interventions/Observational Groups

- Arm 1: **Procalcitonin based algorithmen for tailoring antibiotictherapy. Retrospective analysis from 01.01.2005 to 31.12.2009**

Characteristics

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

Primary Outcome

Retrospective analyses
1. 28-day-Mortality
2. Days on Antibiotictherapy

Secondary Outcome

1. Lenght of stay in Intensiv Care Unit 2. Ventilation hours 3. Re-infection rate 4. antibiotic cost

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Westküstenklinikum Heide, Klinik für Anästhesiologie und operative Intensivmedizin, Heide**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2010/05/01**
- Target Sample Size: **150**
- 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

Severe sepsis and septic shock under antibiotic therapy

Exclusion criteria

known pregnancy; bone-marrow transplant or patient under chemotherapy; infections for which long-term antibiotic treatment is strongly recommended (e.g. infective endocarditis, tuberculosis, anterior mediastinitis after cardiac surgery) and do- not-resuscitate orders

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

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

Westküstenklinikum Heide

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

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25746 Heide
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2011/12/15**

Trial Publications, Results and other documents

- Paper **Hohn A et al. BMC Infect Dis 2013**

** 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.*