PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

Jena Sepsis Registry - a Sepsis-registry for Long Term Outcomes

Trial Acronym

JenaSepsisReg

URL of the trial

[---]*

Brief Summary in Lay Language

Despite the burden of severe sepsis and septic shock deficiencies in the quality of sepsis management are recognized. Investigators present a population-based registry with easy feasibility as part of German Center for Sepsis Control & Care (CSCC). All ICU patients of the Jena University Hospital, Germany will be screened for inclusion (severe sepsis or septic shock). Baseline data on ICU- and hospital care will be extracted from patient records at ICU discharge. The primary outcome is change in all-cause mortality from baseline to follow up at 6, 12, 24, 36, 48 and 60 months after diagnosis of sepsis. Follow-up data will be collected from the primary care provider of the patient. The registry may provide valid data on quality in sepsis care.

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00008342**
- Date of Registration in DRKS: **2016/03/11**
- Date of Registration in Partner Registry or other Primary Registry: **2014/06/11**
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Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT02165501 (ClinicalTrials.gov)**
- Sponsor-ID: **3218-08/11 (University of Jena)**
- Other Secondary-ID: **FZ 01 E0 1002**

Health condition or Problem studied

- Free text: **Severe Sepsis or Septic Shock (ICD-10-GM, R65.0, R65.1)**
- ICD10: **R65.0 - Systemic Inflammatory Response Syndrome of infectious origin without organ failure**
- ICD10: **R65.1 - Systemic Inflammatory Response Syndrome of infectious origin with organ failure**

Interventions/Observational Groups

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **[---]***
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **[---]***
- Purpose: **[---]***
- Assignment: **[---]***
- Phase: **N/A**

Study Type: **Non-interventional**

Study Type Non-Interventional: **Observational study**

Allocation: **[---]***

Blinding: **[---]***

Who is blinded: **[---]***

Control: **[---]***

Purpose: **[---]***

Assignment: **[---]***

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- all cause mortality; time frame: change from baseline to 6,12, 24, 36, 48 and 60 months after ICU discharge; based on data from hospital records as well as patient records of the primary care provider.

Secondary Outcome

[---]*

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Jena University Hospital, Jena**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2011/01/31**
- Target Sample Size: **2000**
- Monocenter/Multicenter trial: **[---]***
- National/International: **[---]***

Inclusion Criteria

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

Additional Inclusion Criteria

- Patients treated in one of the ICUs will be enrolled if they were 18 years or older and fulfill the diagnostic criteria of severe sepsis or septic shock (ICD-10-GM, R65.0, R65.1) (19), (20).

- Diagnosis of severe sepsis or septic shock requires the following criteria: a microbiologically documented and/or clinically evident infection, at least two of the four criteria of the systemic inflammatory response syndrome (SIRS) and at least one new organ dysfunction, remote from the site of infection.

Exclusion criteria

-

Addresses

- **Primary Sponsor**

  University of Jena

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

- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

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

Status

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

Trial Publications, Results and other documents

- Further trial documents **[---]***

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 1
- Last processed date by ClinicalTrials.gov: 2015/05/04

** 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.*