Trial Description

Title

Early Detection of LIFE-threatening Infections – Rapid Diagnosis by a multivalent innovative Biomarkerpanel on a mobile Point-of Care (POC) device Biomarker for Early Sepsis Diagnosis "BEdSide"

Trial Acronym

LIFE-POC-BEdSide

URL of the trial

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Brief Summary in Lay Language

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Brief Summary in Scientific Language

The aim of this project is the reduction of mortality and morbidity of critically ill patients with infectious inflammation by the combined use of biomarkers for risk assessment, early diagnosis and therapy evaluation using a new mobile multiplex point-of-care (POC) device.
This cohort study is designed to investigate the clinical utility of an innovative biomarker panel for the early identification of patients with sepsis in acute settings. Early blood samples of patients with suspected sepsis will be obtained and a prototype mobile point-of-care (POC)-device for eligible biomarkers will be developed. In the central emergency departments of the University Hospital Jena and the Charité Universitätsmedizin Berlin, blood samples from a total of 1500 patients will collected and analyzed. In addition the biomarker panel will be tested retrospectively in blood samples from septical patients included into the HYPRESS-Study.
Measured biomarkers will be evaluated with respect to their utility in early diagnosis, risk stratification and therapy management and a biomarker panel with high clinical relevance will be determined.

Organizational Data

- DRKS-ID: **DRKS00011188**
- Date of Registration in DRKS: **2016/10/20**
- 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.: **4912-08/16 , Ethikkommission der Friedrich-Schiller-Universität Jena an der Medizinischen Fakultät**

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Secondary IDs

Health condition or Problem studied

- ICD10: **A41 - Other sepsis**

Interventions/Observational Groups

- Arm 1: **This cohort study is designed to investigate the clinical utility of an innovative biomarker panel for the early identification of patients with sepsis in acute settings. Early blood samples of patients with suspected sepsis will be obtained and a prototype mobile point-of-care (POC)-device for eligible biomarkers will be developed. In the central emergency departments of the University Hospital Jena and the Charité Universitätsmedizin Berlin, blood samples from a total of 1500 patients will collected and analyzed. In addition the biomarker panel will be tested retrospectively in blood samples from septical patients included into the HYPRESS-Study.**
  Measured biomarkers will be evaluated with respect to their utility in early diagnosis, risk stratification and therapy management and a biomarker panel with high clinical relevance will be determined.
  In the emergency room and in case of further laying, blood samples are taken, documentation of the relocation / discharge diagnoses.
  Follow-up of the patient during the stay (96h):
  documentation of the following parameters: sepsis / septic shock according to the current definition considering the SOFA score as well as the definition according to ACCP / SCCM consensus conference, organ dysfunction, organ replacement procedure, laboratory parameters concerning infection and organ dysfunction, infection focus, microbiology results, outpatient care, relocation from normal station, intensive care unit (ITS), intermediate care station (IMC), and hospital-, intensive care unit / intermediate care unit length of stay, status at discharge.

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

Occurrence of sepsis within 96 hours

Secondary Outcome

Septic shock within 96h, hospital / 28 day mortality, infection focus, microbiological examination results, organdysfunction, organs replacement, clinical and laboratory findings and medication during inpatient stay, transfer to ITS, ITS days, KH days, maximum SOFA score

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Notaufnahme, Jena**
- University Medical Center **Notaufnahme, Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/12/19**
- Target Sample Size: **1500**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

Glasgow Coma Scale <15, respiratory rate ≥ 22 / min, systolic blood pressure ≤ 100 mmHg

Exclusion criteria

Known pregnancy, acute myocardial infarction, leading traumadiagnosis, patients with therapy with limited life expectancy <28 days, already participants of the study with pre-stay

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

■ **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Kapelle-Ufer 1
10117 Berlin
Germany

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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.*