Trial Description

Title

Determination of antibiotic concentrations in interstitial space fluid of muscle and subcutis in septic patients including a pilot phase

Trial Acronym

DAC-septic patient

URL of the trial

[---]*

Brief Summary in Lay Language

To evaluate feasibility of antibiotic concentration determination in interstitial space fluid of muscle and subcutis in septic patients including a pilot phase to explore pharmacokinetic variability and to determine sample size for the main study.

Brief Summary in Scientific Language

To evaluate feasibility of antibiotic concentration determination in interstitial space fluid of muscle and subcutis in septic patients including a pilot phase to explore pharmacokinetic variability and to determine sample size for the main study.

Organizational Data

- DRKS-ID: **DRKS00005046**
- Date of Registration in DRKS: **2013/07/09**
- 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.: **11-4691 , Ethik-Kommission der Medizinischen Fakultät der Universität Duisburg-Essen**

Secondary IDs

Health condition or Problem studied

- ICD10: **A41.9 - Sepsis, unspecified**

Interventions/Observational Groups

- Arm 1: **Tissue concentrations of antibiotic were obtained by microdialysis and analysed with HPLC during the 1 - 4 day. Since both are different in sepsis, the protein binding and the distribution of water volume as a function of stage of sepsis, the antibiotics effective concentrations during sepsis should be different. This study investigated the hypothese that the tissue concentration of antibiotics during sepsis ist below the MHK. Therefore be measured in this study, whether the antibiotics are adequate dosage during different phases of sepsis.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Area under the concentration time curve (AUC), maximum concentration (Cmax), half-life (t1/2) in the microdialysate and plasma after single dose and at steady state.

Secondary Outcome

Assoziation of 30 days survival in patients withe sepsis dependent on tussues concentrations of antibiotics. Plasma will be revieled with microdialysis and analysed with HPLC.

Countries of recruitment

- DE **Germany**
- AT **Austria**

Locations of Recruitment

- University Medical Center **Klinik für Anästhesoilogie, Intensivmedizin u. Schmerztherapie, Knappschaftskrankenhaus Bochum, 44892 Bochum**
- University Medical Center **Klinik für Anästhesiologie, Würzburg**
- University Medical Center **Klinik für Anästhesiologie, Wien/Österreich**
- University Medical Center **Klinik für Anästhesiologie, Essen**
- University Medical Center **Klinik für Anästhesiologie, Leipzig**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2013/11/30**
- Target Sample Size: **20**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

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

Additional Inclusion Criteria

Severe sepsis or septic shock as diagnosed according to the criteria of ACCP/SCCM and the MAXSEP Study within 24 hours:

Exclusion criteria

Age < 18 years

Addresses

- **Primary Sponsor**

  Knappschaftskrankenhaus Bochum
  Klinik für Anästhesiologie, Intensivmedizin und Schmerztherapie
  Mr. Prof. Dr. med. Michael Adamzik

Primary Sponsor

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■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

■ **Private sponsorship (foundations, study societies, etc.)**

Paul-Ehrlich-Stiftung
c/o Deutsche Bank AG

Taunusanlage 17

Private sponsorship (foundations, study societies, etc.)

Paul-Ehrlich-Stiftung
c/o Deutsche Bank AG

Taunusanlage 17
60325 Frankfurt am Main
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **www.paul-ehrlich-stiftung at pvw.uni-frankfurt.de**
URL: **[---]***

Status

- Recruitment Status: **Recruiting planned**
- 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.*