Trial Description

Title

Examination of predictive parameters for early diagnosis and therapy of organ failure in patients with sepsis.

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

[---]*

Brief Summary in Scientific Language

Therefore this single-centre study aimed at investigating the effect of differentially regulated proteins in the blood and urine for early diagnosis of acute organ failure in patients with sepsis.
The urine and blood samples will then be examined with molecular biological techniques (Proteomics).

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00008550**
- Date of Registration in DRKS: **2015/07/02**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Pending/not yet approved**
- (leading) Ethics Committee Nr.: **15-104 , Ethik-Kommission der Medizinischen Fakultät der Universität zu Köln**

Secondary IDs

Health condition or Problem studied

- ICD10: **A41.9 - Sepsis, unspecified**
- ICD10: **R57.2 - Septic shock**

Interventions/Observational Groups

- Arm 1: **60 patients will be enrolled in this study. In these patients samples of blood und urine are taken once daily during a period of 20 days.**
  The urine and blood samples will then be examined with molecular biological techniques (Proteomics).
  The protein are separated by standard agarose gel electrophoresis. The protein identification becomes possible by mass spectroscopy.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- 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

Early detection of organ failure in patients with sepsis.

Secondary Outcome

The initiation and maintenance of renal replacement therapy.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Köln**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2015/07/01**
- Target Sample Size: **60**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **99 Years**

Additional Inclusion Criteria

Patients with sepsis in accordance with the criteria of the German Sepsis Society.

Exclusion criteria

Patientes with dialysis-dependent kidney insufficiency
Pregnancy

Addresses

- **Primary Sponsor**

  Klinik für Anästhesiologie und Operative Intensivmedizin
  Mr. Priv.-Doz. Dr. med. Jochen Hinkelbein
  Kerpenerstr. 62
  50937 Köln
  Germany

Primary Sponsor

Klinik für Anästhesiologie und Operative Intensivmedizin
Mr. Priv.-Doz. Dr. med. Jochen Hinkelbein
Kerpenerstr. 62
50937 Köln
Germany

Telephone: **+49 221 478-82058**
Fax: **[---]***
E-mail: **jochen.hinkelbein at uk-koeln.de**
URL: **[---]***

■ **Contact for Scientific Queries**

Klinik für Anästhesiologie und Operative Intensivmedizin
Mr. Priv.-Doz. Dr. med. Jochen Hinkelbein
Kerpenerstr. 62
50937 Köln
Germany

Telephone: **+49 221 478-82058**
Fax: **[---]***
E-mail: **jochen.hinkelbein at uk-koeln.de**
URL: **[---]***

■ **Contact for Public Queries**

Klinik für Anästhesiologie und Operative Intensivmedizin
Mr. Priv.-Doz. Dr. med. Jochen Hinkelbein
Kerpenerstr. 62
50937 Köln
Germany

Telephone: **+49 221 478-82058**
Fax: **[---]***
E-mail: **jochen.hinkelbein at uk-koeln.de**
URL: **[---]***

■ **Collaborator, Other Address**

Klinik für Kardiologie, Angiologie, Pneumologie und internistische Intensivmedizin.
Mr. Dr. med. Christoph Adler
Kerpenerstr. 62
50937 Köln
Germany

Telephone: **[---]***

Collaborator, Other Address

Klinik für Kardiologie, Angiologie, Pneumologie und internistische Intensivmedizin.
Mr. Dr. med. Christoph Adler
Kerpenerstr. 62
50937 Köln
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **christoph.adler at uk-koeln.de**
URL: **[---]***

Sources of Monetary or Material Support

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

Uniklinik Köln
Mr.
Kerpenerstr. 62
50937 Köln
Germany

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