

Trial Description

Title

Change of microcirculation with haemoadsorption in patients with sepsis and septic shock

Trial Acronym

MiHaS

URL of the trial

[---]*

Brief Summary in Lay Language

Sepsis is a life-threatening disease caused by an exaggerated and misdirected immune reaction of the body to an infection. In the course the blood circulation decreases which has also an impact on the mucous membranes. The aim of this study ist to investigate, whether the use of a Cytokine-Adsorber that shall reduce the exaggerated immune reaction improves the blood circulation in mucous membranes as well as the liver function.

Brief Summary in Scientific Language

Sepsis is a life-threatening organ disfunction caused by an inadequate, misdirected host response to an infection. In the course of the sepsis the microcirculation in the mucosa is reduced. The aim of this study is to investigate, whether the use of a Cytokine-Adsorber and the connected reduction of all pro- and anti inflammatory active cytokines improves the mucosal microcirculation as well as liver function.

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

No

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00017211**
- Date of Registration in DRKS: **2019/07/30**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

DRKS-ID: **DRKS00017211**

Date of Registration in DRKS: **2019/07/30**

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Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2019-440 , Ethikkommission der Medizinischen Fakultät der Ruhr-Universität Bochum, Sitz Bad Oeynhausen**

Secondary IDs

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Patients with sepsis and haemoadsorption**

Characteristics

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

Primary Outcome

Change of mucosal microcirculation during haemoadsorption.

Secondary Outcome

Change of liver function during haemoadsorption.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätsklinik für Anästhesiologie, op. Intensivmedizin, Rettungsmedizin, Schmerztherapie der Ruhr-Universität Bochum, Campus OWL, Klinikum Herford, Herford**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/03/20**
- Target Sample Size: **30**
- 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

- 1) **presence of sepsis according to the current sepsis 3-definition or presence of septic shock according to the current sepsis 3-definition**
- 2) **presence of an anus praeter**

Exclusion criteria

- 1) **pregnancy**
- 2) **breastfeeding women**

Addresses

■ **Primary Sponsor**

**Universitätsklinik für Anästhesiologie, operative Intensivmedizin,
Rettungsmedizin, SchmerztherapieKlinikum Herford AÖR
Schwarzenmoorstraße 70**

32049 Herford

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URL: <https://www.klinikum-herford.de/>

■ **Contact for Scientific Queries**

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■ **Contact for Public Queries**

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Sources of Monetary or Material Support

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

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■ **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

**CytoSorbents Europe GmbH
Müggelseedamm 131
12587 Berlin
Germany**

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Fax: [---]*

E-mail: [---]*

URL: [---]*

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.