Trial Description

Title

Myoglobin Clearance in CVVHD and CVVHDF with regional citrate antiocoagulation

Trial Acronym

CIMIC-2

URL of the trial

http://intensivmedizin.uniklinikum-leipzig.de/

Brief Summary in Lay Language

**Critical ill patients (e.g. sepsis, shock...) develope often acute renal injury. It`s not possible that the kidney detoxicate and keep up the fluid balance adequate. For that reason the blood is cleared by dialyses.
Addition of citric acid blocks the blood clotting in the dialysis without increasing the risk of bleeding complications in the body.
That trial compares if a new diaylsis filter (CVVHD-Emic) equally to the standard technique (CVVHDF) clean up particle with a middle molecule mass (myoglobin) from the blood. Both study groups get an anticoagulation with citric acid.**

Brief Summary in Scientific Language

**Critical ill patients with indication for renal replacement therapy will be included. They will be randomized in two groups with a 1:1 ratio. Group A will be treated with CVVHDF CiCa Ultraflux AV 1000S and group B with CVVHD CiCa Ultraflux EMiC2 (Fresenius medical care). A total number of 75 patients will be included.
We hypothesize, that CVVHD using the EMiC2-filter is at least as effective as CVVHDF using normal high cut-off filters in eliminating myoglobine using regional citrate anticoagulation.**

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00012407**

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- Date of Registration in DRKS: **2017/05/23**
- 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.: **293/16-ek , Ethikkommission an der Medizinischen Fakultät der Universität Leipzig**

Secondary IDs

Health condition or Problem studied

- ICD10: **N17.01 - [generalization N17.0: Acute renal failure with tubular necrosis]**

Interventions/Observational Groups

- Arm 1: **Dialysis usingCVVHDF CiCa Ultraflux AV 1000S**
- Arm 2: **Dialysis using CVVHD CiCa Ultraflux EMiC2**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject**
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Myoglobin clearance after 1h, 6h, 12h, 24h and 48h.

Secondary Outcome

Urea, Creatinin, β2 microglobulin , Il-6 and human albumin clearance after 1h, 6h, 12h, 24h and 48h.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Interdisziplinäre internistische Intensivstation, Leipzig**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/05/02**
- Target Sample Size: **70**
- 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

inidcation for renal replacement therapy

Exclusion criteria

• Indication for therapeutic anticoagulation for different reasons
• Age < 18 years
• High risk of citrate accumulation (e.g. liver dysfunction)
• Contraindication for RRT (e.g. palliative situations)
• Refusal of the patient
• Moribund patient or high risk to die in the first 48 hours
• Pregnant and breast feeding women
• Inclusion in other studies

Addresses

■ **Primary Sponsor**

Universitätsklinikum Leipzig AöR
Liebigstraße 18
04103 Leipzig
Germany

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

■ **Contact for Scientific Queries**

Universitätsklinikum Leipzig AöR
Interdisziplinäre Internistische Intensivmedizin Leiter: Prof. Dr. med. Sirak Petros
Dr. med. Lorenz Weidhase
Liebigstraße 20
04103 Leipzig
Germany

Telephone: **0341/9712706**
Fax: **0341/9712719**
E-mail: **Lorenz.Weidhase at medizin.uni-leipzig.de**
URL: **[---]***

■ **Contact for Public Queries**

Interdisziplinäre Internistische Intensivstation, Universitätsklinikum Leipzig
Mr. Dr.med. Lorenz Weidhase
Liebigstraße 20
04103 Leipzig
Germany

Telephone: **0341-9712706**
Fax: **[---]***
E-mail: **lorenz.weidhase at medizin.uni-leipzig.de**
URL: **[---]***

Sources of Monetary or Material Support

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

Fresenius Medical Care Deutschland GmbH

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

Fresenius Medical Care Deutschland GmbH
Else-Kröner-Straße 1
61352 Bad Homburg v.d.H
Germany

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

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2018/09/30**

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.*