PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Citrate based CVVH in Patients with Acute Renal Failure: Comparison of a New Citrate Based Hemofiltration Solution vs. Standard Bicarbonate Based Hemofiltration Solution.

Trial Acronym

[---]*

URL of the trial

http://-

Brief Summary in Lay Language

Study to compare the efficacy and safety of an innovative renal replacement therapy for patients with acute renal failure against the established standard procedure.

Brief Summary in Scientific Language

Study to compare continuous veno-venous hemofiltration with citrate buffered hemofiltration solution and regional citrate anticoagulation against continuous veno-venous hemofiltration with bicarbonate buffered hemofiltration solution and systemic heparin anticoagulation.

Organizational Data

- DRKS-ID: **DRKS00000224**
- Date of Registration in DRKS: **2009/10/12**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2377 , Ethik-Kommission an der Medizinischen Fakultät der Heinrich-Heine-Universität Düsseldorf**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1111-0197**
- EudraCT-No.

(for studies acc. to Drug Law): **2005-004734-40**

- BfArM-No.: **4022095**
- Sponsor-ID: **HD/HF-CA/01/D (Fresenius Medical Care Deutschland GmbH)**

Health condition or Problem studied

- ICD10: **N17 - Acute renal failure**

Interventions/Observational Groups

- Arm 1: **Continuous veno-venous hemofiltration with HF-Citrate 39-210T and regional citrate anticoagulation**
- Arm 2: **Continuous veno-venous hemofiltration with MultiBic 2mmol/L Kalium and systemic heparin anticoagulation**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

Acid-base status on day three after initiation of the CVVH treatment and on each consecutive day.

Secondary Outcome

Therapeutic safety of the citrate based HF solution in comparison to bicarbonate HF solution with particular focus on adverse events like bleeding complications, heparin induced thrombocytopenia and mortality, acid-base derangements and systemic ionised calcium levels.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2004/11/01**
- Target Sample Size: **120**
- 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

Written informed consent given, Adult patients >18 years, Diagnosis of acute renal failure and indication for renal replacement therapy as assessed by volume overload, not correctable by diuretics in spite of adequate blood pressure and creatinine > 1.2 mg/dl, or increase of serum creatinine > 2.5 mg/dl or BUN > 50 mg/dl, or increase of serum potassium > 5.5 mmol/l due to oligo-anuria, Patients which at the time of inclusion have not yet started with the renal replacement therapy, Arterial line as vascular access, Mechanical ventilation

Exclusion criteria

HIT II (heparin-induced thrombocytopenia type 2), Need to continue effective systemic heparin anticoagulation with an aPTT > 20% above the upper limit of the normal range , Metabolic alkalosis as defined by a pH > 7.50 and base excess of > +4 mmol/L, Pregnancy, lactation period, Patient on chronic renal replacement therapy, Participation in another study during the preceding 3 months, Previous participation in the same study

Addresses

- **Primary Sponsor**

  Fresenius Medical Care Deutschland GmbH

Primary Sponsor

Fresenius Medical Care Deutschland GmbH
Daimlerstrasse 15
61352 Bad Homburg
Germany

Telephone: **06172 6092271**
Fax: **[---]***
E-mail: **rainer.himmele at fmc-ag.com**
URL: **www.fmc-ag.de**

■ **Contact for Scientific Queries**

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Sources of Monetary or Material Support

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

Fresenius Medical Care Deutschland GmbH
61352 Bad Homburg
Germany

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

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

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61352 Bad Homburg
Germany

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

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2008/01/31**

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.*