

Trial Description

Title

middle molecular clearance in citrate-based dialysis using a conventional vs. high-cutoff dialyzer

Trial Acronym

CIMIC

URL of the trial

[---]*

Brief Summary in Lay Language

This prospective randomized trial should investigate, if a large-pored dialysator is superior in elimination of middle molecules. Critical ill patients requiring dialysis caused by renal failure will be randomized in group A (conventional citrate anticoagulation) and group B (citrate anticoagulation and large-pored EMiC®2 dialyzer).

Brief Summary in Scientific Language

This prospective and randomised study should investigate the clearance of middle molecules in CVVHD with regional citrate anticoagulation using conventional or large-pored EMiC®2-dialyzer . Maybe the use of EMiC®2-dialyzer could aggregate the advantages of regional citrate anticoagulation and CVVH.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00005254**
- Date of Registration in DRKS: **2013/11/26**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
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Ethics Approval/Approval of the Ethics Committee: **Approved**

- (leading) Ethics Committee Nr.: **447/12-24092012** , **Ethikkommission an der Medizinischen Fakultät der Universität Leipzig**

Secondary IDs

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **CVVHD with regional citrate anticoagulation: therapy period: max. 72h, 5 blood samples ahead and after dialyzer**
- Arm 2: **CVVHD with regional citrate anticoagulation using large-pored EMiC® 2-dialyzer: therapy period: max. 72h, 5 blood samples ahead and after dialyzer**

Characteristics

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

Primary Outcome

β2-Mikroglobulin Clearance after 1 h, 6 h, 12 h, 24 h und 48 h (estimated by serum levels before and after dialyzer)

Secondary Outcome

Clearance of Urea, Creatinin, Myoglobin and IL-6 after 1 h, 6 h, 12 h, 24 h und 48 h (estimated by serum levels before and after dialyzer)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Interdisziplinäre Internistische Intensivmedizin, Leipzig**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/12/01**
- 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: **100 Years**

Additional Inclusion Criteria

acute dialysis dependent renal failure

Exclusion criteria

therapeutic anticoagulation necessary in other indication; younger than 18 years; high risk of citrate accumulation (for instance acute liver failure); refusal of or contraindications for renal replacement therapie; predicted survival less than 48 h; pregnancy or lactation; member in other clinical trials; decline participation in study

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

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

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Else-Kröner-Straße 1
61352 Bad Homburg**

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Telephone: [---]*

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E-mail: [---]*

URL: [---]*

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/05/31**

Trial Publications, Results and other documents

- Paper **Middle molecule clearance with high cut-off dialyzer versus high-flux dialyzer using continuous veno-venous hemodialysis with regional citrate anticoagulation: A prospective randomized controlled trial**

* 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.