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# Liver Citrate Anticoagulation Threshold study

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|---|---|---|
| **Submission date**<br>26/08/2008 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>04/12/2008 | **Overall study status**<br>Completed | |
| **Last Edited**<br>30/09/2015 | **Condition category**<br>Other | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**Protocol serial number**
CVVHD- Ci-Ca-01-EU

## Study information

**Scientific Title**
Citrate anticoagulation during continuous veno-venous haemodialysis (CVVHD) - an observational study

**Acronym**
LCAT study

**Study objectives**

1. Assessment of the safety and efficacy of regional citrate anticoagulation during continuous veno-venous haemodialysis (CVVHD) using multiFiltrate with the Ci-Ca System®
2. Investigation of the impact of liver failure on safety, efficacy and dosing schemes of this procedure

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Ethics Committee of Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin), 27/07/2007, ref: EA1/101/07

### Study design
Prospective observational open multi-centre study

### Primary study design
Observational

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Intensive care patients with renal failure

### Interventions
Every patient will be observed for 72 hours after the start of the Ci-Ca CVVHD treatment. The participation in the study and the data collection will be terminated before 72 hours if the patient does not require a Ci-Ca CVVHD treatment any more.

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome(s)
Main end-points for the safety evaluation is the occurrence of citrate metabolic complications (hypocalcemia, hypercalcemia, alkalosis, acidosis).

For the efficacy evaluation main end-points are: the percentage of functioning filters after 72 treatment hours and post-filter ionized calcium.

### Key secondary outcome(s))
No secondary outcome measures

### Completion date
31/12/2009

## Eligibility

### Key inclusion criteria
1. Adult patients (at least 18 years old, both males and females) treated on intensive care unit (ICU) due to renal failure requiring CVVHD and citrate anticoagulation (treatment with the multiFiltrate Ci-Ca System®)
2. Patient (or his legal representative or the next of kin - according to the local requirements) written informed consent

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Key exclusion criteria
1. Use of regional citrate anticoagulation in the period of 72 hours preceding the enrolment in the study
2. Concomitant participation in another clinical trial
3. Previous participation in the same study

### Date of first enrolment
07/12/2007

### Date of final enrolment
31/12/2009

## Locations

### Countries of recruitment
United Kingdom

Austria

Germany

Norway

Switzerland

### Study participating centre

**Universitätskrankenhaus Charité**
Berlin
Germany
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# Sponsor information

**Organisation**
Fresenius Medical Care (Germany)

**ROR**
https://ror.org/04sk0bj73

# Funder(s)

**Funder type**
Industry

**Funder Name**
Fresenius Medical Care (Germany)

# Results and Publications

## Individual participant data (IPD) sharing plan

**IPD sharing plan summary**
Not provided at time of registration

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/02/2011 | | Yes | No |
| Results article | results | 29/09/2015 | | Yes | No |