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Liver Citrate Anticoagulation Threshold study

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Stanislao Morgera

Contact details
Universitätskrankenhaus Charité
Medizinische Klinik - Nephrologie
Berlin
Germany
10117

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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.

Secondary outcome measures
No secondary outcome measures

Overall study start date
07/12/2007

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

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
Austria

Germany

Norway

Switzerland

United Kingdom

Study participating centre
Universitätskrankenhaus Charité
Berlin
Germany
10117

Sponsor information

Organisation
Fresenius Medical Care (Germany)

Sponsor details
Else-Kröner-Str. 1
Bad Homburg
Germany
61352

Sponsor type
Industry

Website
http://www.fmc-ag.com

ROR
https://ror.org/04sk0bj73

Funder(s)

Funder type
Industry

Funder Name
Fresenius Medical Care (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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