Liver Citrate Anticoagulation Threshold study

Submission date [] Prospectively registered Recruitment status 26/08/2008 No longer recruiting [] Protocol [] Statistical analysis plan Registration date Overall study status 04/12/2008 Completed [X] Results [] Individual participant data Last Edited Condition category 30/09/2015 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-O1-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