High cut-off Continuous venovenous haemodialysis (CVVHD) to improve haemodynamic stability and Organ function scores in patients treated for acute renal failure after Systemic inflammatory response Syndrome (SIRS)/septic shock

Submission date	Recruitment status	Prospectively registered
17/03/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
24/03/2006	Completed	Results
Last Edited	Condition category	☐ Individual participant data
31/12/2021	Urological and Genital Diseases	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Stanislao Morgera

Contact details

Medizinische Klinik mit Schwerpunkt Nephrologie Charite, Campus Mitte Schumannstr. 20/21 Berlin Germany 10117 +49 (0)304 5061 4137 stanislao.morgera@charite.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00875888

Secondary identifying numbers

0000050

Study information

Scientific Title

High cut-off Continuous venovenous haemodialysis (CVVHD) to improve haemodynamic stability and Organ function scores in patients treated for acute renal failure after Systemic inflammatory response Syndrome (SIRS)/septic shock

Acronym

HICOSS

Study objectives

The aim of the study is to evaluate whether high cut-off continuous venovenous haemodialysis (CVVHD) leads to a significant improvement of the haemodynamic status in comparison to CVVHD treatment with conventional high-flux filters.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved by the following ethics committees:

- 1. Campus Charite Mitte, Berlin (ref: 1988/Si. 277) on 11/09/2003
- 2. University Clinic Tubingen (ref: 249/2003G) on 08/04/2004
- 3. Medical University Innsbruck (ref: 231/4.11) on 07/07/2005
- 4. Ethics Committee for Medical Research, Philipps-University Marburg clinic (ref: 19/06) on 15/02/2006

Study design

Double blind randomised prospective controlled multicentre trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Acute renal failure after SIRS/septic shock

Interventions

Continuous venovenous haemodialysis treatment with high-flux or high-cut-off dialysers.

Please note that as of 13/12/2007 the anticipated end date of this trial was extended to 31/12 /2008 due to the enrolment period being extended. The previous anticipated end date of this trial was 31/12/2006.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

- 1. Dosage of vasopressors
- 2. Mean arterial pressure
- 3. Heart rate
- 4. Central venous pressure

Secondary outcome measures

- 1. Sequential Organ Failure Assessment (SOFA) score
- 2. Survival at 28 days
- 3. Length of need for catecholamine application
- 4. Length of need for mechanical ventilation
- 5. Length of need for renal replacement therapy
- 6. Length of stay in intensive care unit (ICU)

Overall study start date

04/02/2004

Completion date

31/12/2008

Eligibility

Key inclusion criteria

- 1. Fulfilling at least two of the SIRS criteria as defined by the American College of Chest Physicians (ACCP)/Society of Critical Care Medicine (SCCM) Consensus Conference
- 2. Having signs of renal dysfunction
- 3. Requirement for catecholamine administration (norepinephrine or others)
- 4. Acute Physiology And Chronic Health Evaluation (APACHE II) score at enrolment greater than or equal to 19 and less than or equal to 30

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

120

Key exclusion criteria

- 1. Lack of written informed consent from patients or a legally authorized surrogate
- 2. Duration of septic shock greater than 4 days
- 3. Hypoproteinaemia (characterized by serum albumin less than 18 g/l)
- 4. End stage renal failure
- 5. Known active malignancy
- 6. Known human immunodeficiency virus (HIV), hepatitis B virus (HBV) or hepatitis C virus (HCV) infection
- 7. Age younger than 18 years or older than 80 years
- 8. Known pregnancy
- 9. Immunosuppression after transplantation
- 10. Participation in another clinical study
- 11. Renal replacement therapy greater than 24 hours before randomisation

Date of first enrolment

04/02/2004

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

Austria

Germany

Study participating centre Medizinische Klinik mit Schwerpunkt Nephrologie

Berlin Germany 10117

Sponsor information

Organisation

Gambro Dialysatoren GmbH (Germany)

Sponsor details

Holger-Crafoord-Str. 26 Hechingen Germany 72379

Sponsor type

Industry

ROR

https://ror.org/05jgtkc28

Funder(s)

Funder type

Industry

Funder Name

Gambro Corporate Research (Germany)

Results and Publications

Publication and dissemination plan

2009 results presented at WFSICCM 2009 https://scholar.google.com/scholar?q=Honore% 20PM%2C%20Clark%20W.%20Novel%20therapeutical%20concepts%20for%20extracorporeal% 20treatment%20of%20hyperinflammation%20and%20sepsis%3A%20immunomodulation.% 20approach%20with%20a%20novel%20high%20Cut-OFF%20membrane%3A%20the% 20SepteX%20membrane.%20In%20Proceedings%20of%2010th%20Congress%20of%20World% 20Federation%20of%20CCU%20%28WFSICCM%29%202009.%20Florence.

Intention to publish date

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration