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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
17/03/2006

Registration date
24/03/2006

Last Edited
31/12/2021

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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