

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00875888

Protocol serial number

000050

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/05jgtkc28>

Funder(s)

Funder type

Industry

Funder Name

Gambro Corporate Research (Germany)

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Not provided at time of registration