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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

**Recruitment status**
No longer recruiting

**Registration date**
24/03/2006

**Overall study status**
Completed

**Last Edited**
31/12/2021

**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**
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

**ClinicalTrials.gov (NCT)**

NCT00875888

### Protocol serial number
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

### 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