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Evaluation of hemodynamic effects of cascade hemofiltration in septic shock

Submission date	Recruitment status	[X] Prospectively registered
09/01/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/02/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
28/02/2008	Infections and Infestations	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1450

Study information

Scientific Title

Study objectives
Evaluation of the hemodynamic improvement using cascade hemofiltration in patients treated for septic shock

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Committee for Protection of Research Subjects (Comité de Protection des Personnes [CPP]) Ile de France VI, approved on 16 July 2007
2. France's Sanitary Safety in Health Products Agency (AFSSAPS), approved on 30 October 2007

Study design
Multi-center, pilot, prospective, parallel-group, randomised controlled study.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Septic shock/ hemofiltration

Interventions
Either standard hemofiltration or Cascade hemofiltration (2 types of membrane evaluated)

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Number of days without catecholamines at the 28th day of randomization

Secondary outcome measures
1. Rate of decrease of catecholamines during the first 72h
2. Number of days without mechanical ventilation at the 90th day
3. Number of days without Renal Replacement Therapy (RRT) at the 90th day
4. Number of days without ICU requirement at the 90th day
5. Death or survivor status at the 90th day

Overall study start date
01/03/2008

Completion date
01/03/2011

Eligibility

Key inclusion criteria
1. Patient with a septic shock diagnosed by the medical staff team
2. Patient mechanically ventilated and treated by high doses of catecholamines after adequate fluid administration (superior or equal to 1.0 mg/h of norepinephrine or epinephrine) for more than 120 minutes and <24h
Note: Patients with renal failure (treated or not) can be included

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
60

Key exclusion criteria
1. Age (years) <18 or >85
2. Weight >120 kg
3. Thrombocytopenia 50< G/l or Neutrophils <0.5 Giga/l
4. Contra indication to heparin anticoagulation
5. Patient requiring catecholamines (epinephrine or norepinephrine superior or equal to 1 mg/h) for >24h
6. Patient admitted to the Intensive Care Unit (ICU) superior or equal to 7 days before the inclusion criteria
7. Patient with intercurrent disease limiting his/her self-sufficiency (need of help before septic shock)
8. Inclusion (<28 days) in another study interfering with the goals of the current investigation
9. Pregnancy and patient under guardianship
10. Immune compromised patients (e.g., being treated for cancer, treated by immunosuppressors or steroids, AIDS)

Date of first enrolment
01/03/2008

Date of final enrolment
01/03/2011

Locations

Countries of recruitment
France

Study participating centre
Gambro Industries
Lyon
France
69357

Sponsor information

Organisation
Gambro Industries, Clinical Affairs Department (France)

Sponsor details
61 Avenue Tony Garnier
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Sponsor type
Industry

ROR
https://ror.org/01mgtdr23

Funder(s)

Funder type
Industry

Funder Name
Gambro Industries (International)

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