

Evaluation of hemodynamic effects of cascade hemofiltration in septic shock

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

Protocol serial number
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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

Number of days without catecholamines at the 28th day of randomization

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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)

ROR

<https://ror.org/01mgtdr23>

Funder(s)

Funder type

Industry

Funder Name

Gambro Industries (International)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration