

COMbining Plasmafiltration and Adsorption Clinical Trial: efficacy and safety of coupled plasma filtration adsorption for septic shock in the intensive care unit

Submission date 31/05/2006	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 11/07/2006	Overall study status Completed	☐ Protocol
Last Edited 10/01/2014	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Sergio Livigni

Contact details
Servizio Anestesia e Rianimazione B-DEA
Ospedale San Giovanni Bosco
Piazza del Donatore di Sangue 3
Torino
Italy
10148
+39 (0)11 240 2265
sergio.livigni@aslto4.it

Additional identifiers

ClinicalTrials.gov (NCT)
NCT00332371

Protocol serial number
4817

Study information

Scientific Title

COMbining Plasmafiltration and Adsorption Clinical Trial: efficacy and safety of coupled plasma filtration adsorption for septic shock in the intensive care unit - an open-label randomised controlled multi-centre trial

Acronym

COMPACT

Study objectives

To clarify whether the application of coupled plasma filtration adsorption (CPFA) in addition to the current clinical practice is able to reduce mortality of septic shock patients in intensive care unit (ICU).

Please note that extensive amendments have been made to this trial record as of 24/04/2009. They include the following:

1. The scientific title has been added
2. The anticipated end date has been updated from 30/09/2008 to 31/12/2010

All other amendments are recorded in the relevant fields.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Ethical Committee for Local Business Health, Piemonte Region (Comitato Etico Azienda Sanitaria Locale 4 Regione Piemonte) as of 27/06/2006, reference number: 229/10/06

Primary study design

Interventional

Study design

Open-label randomised controlled multi-centre trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Septic shock

Interventions

Coupled plasma filtration adsorption (CPFA) versus standard clinical practice.

Added as of 24/04/2009:

The intervention lasts 10 hours/day for a total of 5 days of treatment. The follow-up ends on the date of discharge from the last hospital or after 90 days from randomisation in patients discharged after 90 days.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Hospital mortality

Added as of 24/04/2009:

Total duration of follow-up: until 90 days after the randomisation of the last patients recruited.

Key secondary outcome(s)

1. Mortality within 90 days from randomisation
2. New organ failures, assessed by Sequential Organ Failure Assessment (SOFA) score during the ICU stay
3. Days not spent in the ICU during the first 30 days from randomisation

Please note that the method and timepoint of assessment for the outcome measure "New organ failures" were added as of 24/04/2009.

Completion date

31/12/2010

Eligibility**Key inclusion criteria**

All patients admitted to the ICU in septic shock or that develop septic shock while in the ICU

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Patients with any of the following characteristics::

1. Age less than 18 years
2. Pregnancy
3. Cardiopulmonary resuscitation
4. Cerebral coma (Glasgow coma score [GCS] <8 due to organic cerebral diseases, irrespective of their surgical, non-surgical, or trauma origin)
5. Metastatic cancer
6. Presence of relative or absolute contraindications to CPFA

7. Estimated life expectancy less than two weeks
8. Already included in the study
9. Admission from another ICU where the patient has been admitted for more than 24 hours
10. Absence of informed consent

Date of first enrolment

15/06/2006

Date of final enrolment

31/12/2010

Locations

Countries of recruitment

Italy

Study participating centre

Servizio Anestesia e Rianimazione B-DEA

Torino

Italy

10148

Sponsor information

Organisation

Italian Group for the Evaluation of Interventions in Intensive Care Medicine (GiViTI)

Funder(s)

Funder type

Research organisation

Funder Name

Mario Negri Institute for Pharmacological Research (Italy) (ref: 4817)

Funder Name

BELLCO s.r.l (Italy)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/01/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes