ISRCTN24534559 https://doi.org/10.1186/ISRCTN24534559

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

Registration date
11/07/2006

Overall study status
Completed

Last Edited
10/01/2014

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.giviti.marionegri.it

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00332371

Secondary identifying numbers
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

Study design
Open-label randomised controlled multi-centre trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Patient information can be found at: http://www.giviti.marionegri.it/Download/SchedaInformativaCOMPACT[IT].zip

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 measure
Hospital mortality

Added as of 24/04/2009:
Total duration of follow-up: until 90 days after the randomisation of the last patients recruited.

Secondary outcome measures
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.

Overall study start date
15/06/2006

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

Age group
Adult

Sex
Both

Target number of participants
330

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)

Sponsor details
Laboratorio di Epidemiologia Clinica
Istituto di Ricerche Farmacologiche
Mario Negri
Villa Camozzi
Via Camozzi 3
Ranica (BG)
Italy
24020
+39 (0)35 453 5313
giviti@marionegri.it

Sponsor type
Research organisation

Website
http://www.giviti.marionegri.it

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/01/2014		Yes	No