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Randomised controlled trial comparing 2 small volume resuscitation fluids in the critically ill

Submission date 30/09/2005	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol
Registration date 30/09/2005	**Overall study status** Stopped	[ ] Statistical analysis plan [ ] Results
Last Edited 07/04/2011	**Condition category** Signs and Symptoms	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0025157070

Study information

Scientific Title

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: Sepsis

Interventions
No additional invasive procedures will result from participation in this study, other than currently used as our standard clinical practice. All patients will be receiving continuous infusions of analgesic and sedating agents, intubated and receiving pressure controlled ventilation of the lungs throughout the study period, PaO2 will be kept between 8and 1 kPa and PaCO2 will be maintained between 4.5 and 7.0 kPa. The lung ventilation will be pressure controlled to reach a tidal volume between 6-8 mL/kg. No changes in the ventilator setting will be made during the study period. All patients will be requiring continuous infusions of a vasopressor agent (norepinephrine). A thermistor tipped arterial catheter will be inserted into the femoral artery of appropriate patients, as indicated as part of standard current practice by a non-participating Consultant Intensivist. This catheter allows additional measurement of cardiac output by transpulmonary thermodilution and of derived variables including intrathoracic blood volume index, continuous cardiac output by pulse-contour analysis and SVV. All transducers will be positioned at the mid-axillary line and zeroed to atmospheric pressure. Patient consent or

relative's assent will be sought. Following initial resuscitation period and during period of haemodynamic stability patients will be initially monitored for 15 minutes to establish baseline values.

Subsequently all eligible patients will be randomly allocated to receive either 4mls/kg of HyperHAES or Rescueflow over 5 minutes under continuous monitoring of cardiac filling pressures. The fluid bolus will be administered via distal lumen of the CVP catheter. The allocation to fluid group will be done by a non-participating pharmacist who will also hold the randomisation key. Volume resuscitation is indicated if SVV% >15% but ITBVI < 1200 mls/m2. 250 mls fluid bolus will be given over 5 mins. No changes in vasopressor therapy during period of measurement. Ventilator settings will not be altered. Any established continuous infusion of maintenance fluid or feed will continue at same set rate throughout study period. Standard biometric data will be collected for each patient along with data to calculate the Acute Physiology and Chronic Health Evaluation II score. Type and rate of inotropic infusions will also be documented. If clinical situation demands a non-participating clinician is able to withdraw patients at any time during the 2 hour study period. Once the study period has ended, standard current clinical practice will continue.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2005

Completion date
01/12/2007

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
20 patients over 18 years with severe sepsis or septic shock

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Not Specified

Target number of participants
20

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2005

Date of final enrolment
01/12/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
AintreeTrust
Liverpool
United Kingdom
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Sponsor information

Organisation
Department of Health

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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Aintree Hospitals NHS Trust (UK)

Funder Name
NHS R&D Support Funding

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