

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

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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 8 and 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(s)

Not provided at time of registration

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

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

United Kingdom

England

Study participating centre

AintreeTrust

Liverpool

United Kingdom

L9 7AL

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Aintree Hospitals NHS Trust (UK)

Funder Name

NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration