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Small volume resuscitation with albumin in intensive care

Submission date 06/11/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol
Registration date 19/12/2017	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 11/04/2019	**Condition category** Circulatory System	[_] Individual participant data

Plain English summary of protocol

Background and study aims
Administration of fluids directly into a vein is commonly used to treat low blood pressure in critically ill patients. The aim of such so-called fluid resuscitation is to increase the circulating blood volume to improve the blood flow to body organs. Prolonged fluid resuscitation may, however, lead to fluid accumulation in the tissues, which contributes to organ damage and even increased mortality. Albumin is a natural part of human blood with a high ability to bind water. In the United Kingdom, two different albumin-containing solutions are widely and routinely used for fluid resuscitation; a 5% solution (containing 50 mg albumin per ml) and a concentrated 20% solution (containing 200 mg albumin per ml). Theoretically, the concentrated 20% albumin solution can accomplish the same volume expansion effect as the 5% solution using only one fifth of the administered volume. A reduced volume of fluid administered may ultimately attenuate the severity of organ damage, expedite recovery from the critical illness and reduce mortality. The aim of this study is to test whether fluid resuscitation with 20% albumin solution reduces the accumulation of fluid and organ damage in critically ill patients as compared to fluid resuscitation with the 5% albumin solution.

Who can participate?
Adults aged 18 and older who are in the critical care.

What does the study involve?
Participants in intensive care who are in need of intravenous fluid resuscitation are randomly allocated to receiving either 20% or 5% human albumin solution as their resuscitation fluid for 48 hours from the time of randomisation. The volume of fluid and its rate of delivery will be at the discretion of the treating physician. All other care and interventions are provided according to local policy and the discretion of the treating physician. Participants are followed throughout their hospital stay.

What are the possible benefits and risks of participating?
Participants may benefit from improvements in their symptoms. There are no specific risks to taking part aside from patients providing additional blood samples (approx 12ml per fluid challenge delivered) and those incumbent with human albumin solution. Albumin solutions have been used for resuscitation since the 1940s. An investigation of the safety of albumin solutions

showed that between 1998 and 2000, approximately 107 units of such albumin solutions were administered worldwide. Adverse effects that were directly associated with albumin were an extremely rare event during this observation period. There are, however, more recent reports that the use of (20%) albumin is associated with increased mortality for patients with traumatic brain injury. Accordingly, patients with traumatic brain injury will be excluded from the study. Although albumin is prepared from pooled plasma, albumin preparations currently available are considered to be non-allergenic due to the manufacturing process.

Where is the study run from?
1. Manchester Royal Infirmary (UK)
2. Austin Hospital (Australia)
3. Flinders Medical Centre (Australia)

When is the study starting and how long is it expected to run for?
September 2015 to December 2017

Who is funding the study?
CSL Behring UK Limited (UK)

Who is the main contact?
Dr Jonathan Bannard-Smith
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
2016-001940-20

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32455; ACTRN12615000349549

Study information

Scientific Title
A pilot, randomised, unlinded, feasibility, safety and biochemical and physiological efficacy study of 20% versus 5% human albumin solution for fluid bolus therapy in critically ill adults

Acronym
SWIPE

Study objectives
The aim of this study is to test whether fluid resuscitation with 20% albumin solution reduces the accumulation of fluid and organ damage in critically ill patients as compared to fluid resuscitation with the 5% albumin solution.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yorkshire & The Humber - Sheffield Research Ethics Committee, 11/10/2016, ref: 16/YH/0349

Study design
Randomised; Both; Design type: Treatment, Drug, Not Specified

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Critical care, Primary sub-specialty: Critical Care; UKCRC code/ Disease: Generic Health Relevance/ No specific disease

Interventions
In this prospective physiological feasibility study adult patients in intensive care who are in need of intravenous fluid resuscitation are randomly allocated to receiving either 20% or 5% human albumin solution as their resuscitation fluid for 48 hours from the time of randomisation. The

volume of fluid and its rate of delivery will be at the discretion of the treating physician. All other care and interventions will be provided according to local policy and the discretion of the treating physician.

Participants are followed through their stay in hospital measuring how much fluid they receive and other data concerning vital organ function including the results of additional blood tests and their eventual outcomes.

Intervention Type
Other

Phase
Phase IV

Primary outcome measure
Volume of resuscitation fluid delivered is measured using standard nursing bedside assessment and documentation of all fluid administered at 48 hours.

Secondary outcome measures
1. The cumulative fluid balance is measured using standard nursing bedside assessment and documentation after 48 hours in ICU 2. The amount of vasoactive medication given over the first 4 hours after a fluid bolus and over the first 48 hours in ICU is measured using standard nursing bedside assessment and documentation.
3. The total amount of fluids given over the first 4 hours after a fluid bolus, daily and over the first 48 hours in ICU is measured using standard nursing bedside assessment and documentation.
4. The relative change in haemodynamic variables and blood gas results over the first 4 hours after a fluid bolus is measured using standard data documented on the patients ICU chart just prior to randomisation and then at 1, 2 and 4 hours following.
5. The relative change between baseline and peak creatinine in the first 48 hours after randomization is measured using our institution’s standard renal blood profiles of samples taken just prior to randomisation, and also at 24 and 48 hours later.

Overall study start date
01/09/2015

Completion date
31/12/2017

Eligibility

Key inclusion criteria
1. Admitted to the Department of Intensive Care, Austin Hospital for less than 24 hours or to the Intensive and Critical Care Department of the Flinders Medical Centre for less than 24 hours
2. Age 18 years or greater
3. Need for fluid bolus as determined by the treating clinician
4. Presence of one or more of the following physiological states: systolic BP <90 mmHg, or MAP <65 mmHg, or increasing need for vasopressor drug infusion or pulse pressure variation >12 % or stroke volume variation >12%, or Cardiac index <2.2 L/min/m2 or heart rate >100 or urinary output <20 ml/hr or either rising lactate levels or lactate levels >2 mmol/L or capillary refill time >3 seconds or central venous pressure <8 mmHg

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 400; UK Sample Size: 20

Total final enrolment
321

Key exclusion criteria
1. Confirmed or suspected pregnancy
2. Patients with traumatic brain injury
3. Active bleeding
4. Haemoglobin level <70 g/L
5. People who refuse blood products
6. Patients in whom death is considered imminent (within 24 hours)

Date of first enrolment
01/01/2017

Date of final enrolment
09/03/2017

Locations

Countries of recruitment
Australia

England

United Kingdom

Study participating centre
Manchester Royal Infirmary
Central Manchester University Hospitals
Oxford Road
Manchester
United Kingdom
M13 9WL

Study participating centre
Austin Hospital
145 Studley Road
Heidelberg
Australia
VIC 3084

Study participating centre
Flinders Medical Centre
Flinders Drive
Bedford Park
Adelaide
Australia
SA 5042

Sponsor information

Organisation
Central Manchester University Hoapitals NHS Foundation Trust

Sponsor details
Trust Headquarters
Cobbett House
Manchester Royal Infirmary
Oxford Road
Manchester
England
United Kingdom
M13 9WL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Industry

Funder Name
CSL Behring UK Limited

Funder Name
Austin Medical Research Foundation

Alternative Name(s)
AMRF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Australia

Results and Publications

Publication and dissemination plan
The study will be published in the name of the of the study investigators. The chief investigator will be listed as the first author and other members of the management committee will be listed alphabetically. Funding bodies will be acknowledged in the publication.
Following completion of the study and data analysis the study results will be published in a peer-reviewed critical care journal and presented at local and national intensive care conferences. In addition, we will provide a summary of the study and its findings to the staff of the two study sites.

Intention to publish date
01/06/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to
1. The physiological findings will be of a pilot investigation in nature.
2. The implications of the findings are uncertain beyond those of the main study and only aim to assist clinicians' in perhaps understating more clearly possible impact behind differences in fluid choice that might become apparent from the findings of the study.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V2.2	18/05/2016	19/12/2017	No	No

Results article	results	01/11/2018	11/04/2019	Yes	No
HRA research summary			28/06/2023	No	No