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A trial of crystalloid versus colloid fluid solutions for the resuscitation of patients with severe injuries

Submission date
15/06/2009

Recruitment status
No longer recruiting

Registration date
24/07/2009

Overall study status
Completed

Last Edited
17/03/2017

Condition category
Injury, Occupational Diseases, Poisoning

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

Plain English summary of protocol

Background and study aims:
When a person is badly injured and there is significant loss of blood, one of the most important strategies for aiding recovery is to replace the lost volume of blood with suitable intravenous fluid (fluid resuscitation). There is considerable controversy regarding the nature of the fluid that should be used. Simple salt solutions (crystalloids) are widely used and are recommended on the basis that they are cheap and have few side effects. On the other hand, more complex solutions containing large molecules (colloids) designed to remain in the bloodstream longer are widely supported because they provide faster initial resuscitation with smaller volumes of fluid and this may lead to better outcomes, particularly in terms of swelling of the tissues (oedema). However, the colloids do have some side effects in that they are associated with an increased risk of bleeding, carry a very small risk of severe allergic reactions and have a possible association with kidney injury. The controversy between these two types of fluid relates to the fact that various studies have failed to demonstrate a consistent benefit from the use of colloids and that colloids are significantly more expensive. The aim of this study is to compare resuscitation with crystalloids and colloids in patients who have suffered severe injury (trauma), either blunt (e.g. motor vehicle accidents) or penetrating (e.g. gunshot or stab wounds). The intention is to study the amount of each fluid type required in either blunt or penetrating trauma and to investigate possible differences in patient outcomes as a result of the use of one type of fluid or the other.

Who can participate?
Patients aged 18 to 60 who have suffered sufficiently severe injuries to require a minimum of 3 litres of fluid resuscitation

What does the study involve?
Participants are randomly allocated to undergo fluid resuscitation using either standard crystalloid solution (normal salt solution) or a widely used colloid solution (hydroxy ethyl starch [HES]). All participants are otherwise treated identically in a manner appropriate to the injuries received. The main measurements to be made are the volumes of fluid required in the first 24 hours, including these study fluids, and the requirement for blood and blood products. The

major outcome to study is the speed of recovery of bowel function after injury. Safety markers to examine include markers of kidney damage and measurements of blood clotting. In addition, other factors to measure include the length of stay in intensive care and markers of overall organ function.

What are the possible benefits and risks of participating?
Participants benefit from being treated by experts in the field from the moment they reach the hospital. Side effects from the crystalloid might include fluid overload, with tissue swelling and possible swelling in the abdominal area that may increase the risk of complications from the injury. Side effects related to the colloid might include increased risk of bleeding, a possibility of long-term skin itching and a possibility of kidney injury related to the colloid.

Where is the study run from?
Groote Schuur Hospital (South Africa)

When is the study starting and how long is it expected to run for?
December 2007 to December 2009

Who is funding the study
1. University of Cape Town (South Africa)
2. Fresenius-Kabi (Germany)

Who is the main contact?
Prof. Michael James
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Comparison of crystalloid-blood resuscitation with crystalloid-colloid-blood resuscitation in severe trauma patients: a randomised double-blind trial

Acronym
FIRST (Fluids In Resuscitation of Severe Trauma)

Study objectives
Colloid (hydroxyethyl starch HES 130/0.4 in saline) used for trauma resuscitation is superior to crystalloid (0.9% saline) solutions in terms of volumes required for resuscitation and consequent morbidity, particularly the recovery of gastrointestinal function and the incidence of complications.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Cape Town Research Ethics Committee, 23/01/2007, ref: 217/2006

Primary study design
Interventional

Study design
Randomised single-centre double-blind interventional study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Severe blunt or penetrating trauma

Interventions
1. Intravenous fluid administration to haemodynamic and physiological endpoints as required, 0.9% saline
2. HES 130/0.4 in saline (Voluven®)
Time taken to achieve haemodynamic goals is recorded. Duration of treatment is until study endpoint (return of bowel function) is satisfied; follow-up for 30 days from enrolment or death.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
1. Volumes of fluids required to meet resuscitation goals over the first 24 hours from study entry
2. Time (days) until recovery of bowel function as determined by tolerance of oral of parenteral feeding

Key secondary outcome(s)

1. Days free of gastrointestinal dysfunction during first 30 days
2. Median and maximal sequential organ failure assessment (SOFA) score
3. Length of stay in Intensive Care Unit (LOS in ICU)
4. Fluid volumes used during initial surgical procedures
5. Time to initial achievement of resuscitation target values
6. Intra-abdominal pressure following resuscitation
7. Time to first passage of stool

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Patients suffering severe trauma requiring at least 3 litres of estimated resuscitation fluid admitted to Groote Shuur Hospital Trauma Unit
2. Penetrating or blunt trauma (separately randomised)
3. Aged greater than 18 years and less than 60 years, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
60 Years

Sex
All

Key exclusion criteria
1. Fluid overload pulmonary oedema
2. Known allergy to hydroxyethyl starch
3. Known pre-existing renal failure with oliguria including anuria, severe intracranial bleeding, severe hypernatremia or severe hyperchloremia on admission
4. Severe head injury from which they are unlikely to recover
5. Severe crush injury
6. Unrecordable blood pressure unresponsive to 2 l fluid loading
7. Clinically obvious cardiac tamponade
8. Neurogenic shock (high spinal)
9. Known acquired immune deficiency syndrome (AIDS) or AIDS related complex
10. Patients receiving dialysis treatment
11. Patients admitted greater than 6 hours following injury

12. Patients who have already received non-study colloids
13. Patients taking part in another clinical trial at the same time
14. Patients refusing consent

Date of first enrolment
06/12/2007

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
South Africa

Study participating centre
University of Cape Town
Cape Town
South Africa
7925

Sponsor information

Organisation
University of Cape Town (South Africa)

ROR
https://ror.org/03p74gp79

Funder(s)

Funder type
University/education

Funder Name
University of Cape Town (South Africa) - supported by an unrestricted educational grant from Fresenius Kabi Deutschland GmbH (Germany)

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	01/11/2011		Yes	No