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Clinical role of human albumin in extracorporeal prime

Submission date	Recruitment status	[_] Prospectively registered
09/02/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/02/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
23/07/2014	Circulatory System	

Plain English summary of protocol

Background and study aims?
Due to it being difficult to operate on a beating heart, a heart-lung machine is used to take over for the heart and lungs during open-heart surgery. Starches and/or human albumin are often added to the fluid used to set up the machine before surgery. Human albumin and starch are quite similar in what they do. However, unlike starch, human albumin is a protein found in human blood and it helps to limit any reactions between the blood circulating around the heart-lung machine and the materials that the machine is made from (biopassivation). The passivation effect of albumin has been known to be good for patients having open-heart surgery, but there has been very little research to support its continued use. We want to assess whether not using human albumin in the heart-lung machine has any effect on the care of the patient.

Who can participate?
This study is open to all patients having uncomplicated coronary artery bypass surgery at Eastern Health in St. Johns, Newfoundland, Canada, between 18 and 70 years of age.

What does the study involve?
After informed consent, an investigator will draw a lottery ticket when the patient arrives in the operating room. This will randomly select the patient to one of 2 groups. Group 1 receives the starch, group 2 the human albumin. There will be a few extra blood samples taken during the surgery. These blood samples will be taken while the patient is asleep, and will not require any extra needle sticks to obtain them. This study will take place during the surgery in the operating room. One number will be taken from the patients chart 24 hours after the surgery. The results from these extra blood tests are not available to any clinician to affect treatment while in hospital, and will only be used for this study.

What are the possible benefits and risks of participating?
Both the fluids that we are looking at in this study are used in some combination in essentially every hospital in Canada that performs open-heart surgery. One fluid, human albumin 5% USP, is a fluid made from donated human plasma. As a result, this fluid may contain viruses or other agents that can cause infection and illness. However, the manufacturing process is specifically designed to reduce these agents, if they are present. This risk is very rare. The other fluid, Voluven 6%, is a fluid made from cornstarch. This fluid may cause mild pruritus (itching skin) in

approximately one out of ten people receiving it, which may appear between one and six weeks after exposure, and last for several weeks to months. This fluid may also cause rare anaphylactic allergic reactions. There are no known additional risks caused by adding both these fluids at the same time. There are no anticipated benefits for the individual patient participating in this study.

Where is the study run from
Eastern Health, Memorial University (Canada)

When is study starting and how long is it expected to run for?
From September 2009 to September 2010

Who is funding the study?
Fresenius Kabi (Canada)

Who is the main contact?
Dr. Chander Kamra
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Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Prospective randomized controlled trial of human albumin in biopassivation of extracorporeal circuits

Study objectives
Human albumin is commonly used in extracorporeal prime to provide oncotic pressure to the priming fluid. Another less described indication is its ability to coat the surfaces of the extracorporeal circuit with a protein monolayer, providing biopassivation. Whether this biopassivation has clinically relevant effects is considered.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Investigation Committee, Memorial University (Canada), 17/09/2009, ref. 09.170

Study design
Single-blinded single-center randomized controlled trial

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
Coronary Artery Disease

Interventions
Patients are randomized with a lottery draw into two groups, Control Group and Study Group.

Surgical procedure is identical in both groups, except patients in the Study Group are to receive 50 mL Human Albumin 5% (Plasbumin 5, Talecris Biotherapeutic Ltd., Mississauga, ON), and patients in the Control Group receive 50 mL Plasma-Lyte A in to the heart lung machine.

No further albumin or Voluven 6% is added during the pre-operative or extracorporeal support period. To minimize perfusion conduct variances, one perfusionist will perform the cases.

Blood samples are obtained from the heart lung machine, or in dwelling arterial lines, during the surgery.

The study period will consist of the time the patient is in the operating room, typically four to six hours, and data collection will continue until 24 hours post-operative.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Arterial blood samples are obtained at three intervals. After induction (Prebypass), 30 minutes after bypass initiation (During), and 15 minutes after protamine administration (Postbypass). All samples are assayed within one hour of collection.
2. Total disaggregated platelet counts are measured with an LH750 analyzer (Beckman Coulter, Mississauga, ON) using whole blood collected in 7.2 mg K2 EDTA blood collection tubes (Vacutainer, BD, Franklin Lakes, NJ)
3. Platelet function is measured with a Dade Behring PFA¨C100 analyzer (Newark, DE, USA) using whole blood collected in 0.105 mol/L sodium citrate blood collection tubes (Vacutainer, BD, Franklin Lakes, NJ). Two assays are run for each sample, one using a collagen/epinephrine (Col /EPI) cartridge, and one with a collagen/adenosine (Col/ADP) cartridge. The PFA¨C100 assay requires a reasonable hematocrit to return valid results, therefore patients with hematocrits falling below 25% are excluded from the study
4. A total 24-hour total chest tube drainage value is obtained by measuring the total chest tube drainage 24 hours after entry to the intensive care unit

Secondary outcome measures
1. Demographic information including age, sex, weight are collected
2. Extracorporeal support times and cross clamp times, and urine production

Overall study start date
17/09/2009

Completion date
17/09/2010

Eligibility

Key inclusion criteria
1. Male or female between 18 and 70 years of age
2. Any patient presenting for first time, uncomplicated coronary artery bypass surgery at the institution where the study is being performed

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Total target number of completed participants is 20

Key exclusion criteria
1. Age > 70 years
2. Graft number less than two or more than six
3. Coexistent cardiac disease
4. Re-operation
5. Emergent surgery
6. Pre-operative inotropic support
7. Pre-operative intraaortic balloon pump insertion, or
8. Any deviation from the study protocol

Date of first enrolment
17/09/2009

Date of final enrolment
17/09/2010

Locations

Countries of recruitment
Canada

Study participating centre
Discipline of Anesthesia, Eastern Health
St. John's
Canada
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Sponsor information

Organisation
Memorial University (Canada)

Sponsor details
c/o Dr. Chander Kamra
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Sponsor type

Hospital/treatment centre

ROR
https://ror.org/04haebc03

Funder(s)

Funder type
Industry

Funder Name
Fresenius Kabi (Canada)

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	01/11/2013		Yes	No