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Haemoconcentration of cardiopulmonary bypass blood with Hemosep

Submission date
18/02/2014

Recruitment status
No longer recruiting

Registration date
18/02/2014

Overall study status
Completed

Last Edited
21/02/2017

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
In order for patients to safely undergo cardio-pulmonary bypass for heart surgery, their blood must be diluted so that there is enough circulating volume for both the bypass machine and the patient's body. At the end of bypass this diluted blood is returned to patients. A device called Hemosep can re-concentrate this blood before it is returned to patients. We aim to examine whether concentrating patients blood with Hemosep before returning it leads to a higher haematocrit (higher red blood cell concentration) in patients, compared with patients who receive their diluted blood back.

Who can participate?
Adult patients scheduled to undergo surgery on your heart which requires the use of the cardiac bypass machine.

What does the study involve?
The anaesthesia and surgical procedure will go ahead as standard. We will make no intervention until after the surgery is finished and the support of the heart-lung bypass machine is no longer needed.
Then we will take a blood sample from you, about 10 ml (less than 1 tablespoon) in total, and send it to the lab to measure your red blood cell concentration, number of platelets, and to measure your clotting and coagulation factors. We will collect your leftover diluted blood from the bypass machine, and take about 3 ml (less than 1 teaspoon) of it for analysis in the lab.
You will be randomly allocated to one of two study groups. If you are in our standard group, then you will receive your leftover diluted blood back over about 30-60 minutes, as would normally happen. If you are allocated to the study group, then your leftover diluted blood will be first concentrated using the Hemosep device and then transfused back to you. You will not know which group of the study you are in.
After your bypass blood has been given back to you, we will again take another 10 ml blood sample from you and send it to the lab for analysis.

What are the possible benefits and risks of participating?
It has been demonstrated that concentrating patients excess blood from the heart-lung bypass machine using filtration techniques leads to better outcomes for patients and less need for

blood transfusion after surgery. It is possible that using Hemosep will lead to the same benefits. If we concentrate your blood using the Hemosep, it will take about15 minutes before we will be able to transfuse it back to you. You may need to receive other intravenous fluids during this time, if your anaesthetist or surgeon decides that you do not have enough circulating blood volume. However, the Hemosep requires only about 15 minutes, so this scenario is quite unlikely.

Where is the study run from?
Papworth Hospital NHS Trust, UK.

When is the study starting and how long is it expected to run for?
The study started in November 2013 and is expected to run until April 2014.

Who is funding the study?
Brightwake Ltd, UK.

Who is the main contact?
Andrew Klein, Department of Anaesthesia, Papworth Hospital.

Contact information

Type(s)
Scientific

Contact name
Dr Maurice Hogan

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Additional identifiers

Protocol serial number
15633

Study information

Scientific Title
A randomised controlled pilot study comparing standard fluid management with haemoconcentration of remaining cardiopulmonary bypass blood using the new Hemosep device

Study objectives
In order for patients to safely undergo cardio-pulmonary bypass for heart surgery, their blood must be diluted so that there is enough circulating volume for both the bypass machine and the patient's body. At the end of bypass this diluted blood is returned to patients. Hemosep can re-concentrate this blood before it is returned to patients. We aim to examine whether

concentrating patients' blood with Hemosep before returning it leads to higher haematocrit (higher red blood cell concentration) in patients, compared with patients who receive their diluted blood back.

More details can be found at: http://public.ukcrn.org.uk/search/StudyDetail.aspx?StudyID=15633

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research and Development Department at Papworth Hospital NHS Foundation Trust and East Midlands (Derby) Research Ethics Committee, 09/10/2013, ref:13/EM/0326

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Not specified, Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Cardiovascular; Subtopic: Cardiovascular (all Subtopics); Disease: Cardiovascular

Interventions
Hemosep device vs standard care in the peri-operative period

Haemoconcentration of remaining blood from cardiopulmonary bypass machine.

Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Haematocrit; Timepoint(s): 30-60 minutes after transfusion of blood

Key secondary outcome(s)
1. To evaluate the efficacy of the Hemosep system in reducing allogenic blood transfusion in patients post CPB for cardiac surgery
2. To compare the early postoperative serum levels of red cells, platelets and leukocytes between conventionally treated patients and patients treated with the Hemosep system
3. To compare the early postoperative coagulation indices, clotting factor levels and platelet count between patients treated conventionally and patients treated with the Hemosep system
4. To evaluate the cost effectiveness of the Hemosep system in patients undergoing cardiac surgery

Completion date
30/04/2014

Eligibility

Key inclusion criteria
Adult patients undergoing elective or urgent coronary artery bypass graft surgery (CABG), heart valve surgery, or a combination of CABG and valve surgery will be included.; Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Patients under 18 years of age
2. Patients undergoing emergency surgery
3. Patients with a contraindication to either heparin, protamine or tranexamic acid
4. Patients who might not adequately understand verbal explanations or written information given in English, or who have special communication needs

Date of first enrolment
04/11/2013

Date of final enrolment
30/04/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Clinical Trials, Papworth Hospital NHS Foundation Trust , Papworth Everard
Cambridge

United Kingdom
CB23 3RE

Sponsor information

Organisation
Papworth Hospital NHS Trust (UK)

ROR
https://ror.org/01qbebb31

Funder(s)

Funder type
Industry

Funder Name
Brightwake Ltd (UK)

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	01/05/2015		Yes	No
HRA research summary			28/06/2023	No	No