

Age of BLOOD Evaluation (ABLE) trial in the resuscitation of critically ill patients

Submission date 22/08/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/08/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 15/04/2015	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jacques Lacroix

Contact details
Hôpital Sainte-Justine
3175 Côte Sainte-Catherine
Montreal
Canada
H3T 1C5
+1 (0)514 345 4931 ext. 5556
jacques_lacroix@sss.gouv.qc.ca

Additional identifiers

Protocol serial number
MCT-90648

Study information

Scientific Title
Age of BLOOD Evaluation (ABLE) trial in the resuscitation of critically ill patients: a multicentre randomised controlled superiority clinical trial

Acronym

ABLE

Study objectives

The transfusion of fresh leuko-reduced red cells (stored for less than 8 days) will lead to a 5% or greater improvement in 90 day all cause mortality and clinically important decreases in morbidity in a vulnerable population of critically ill patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethics Committee of Hôpital Sainte-Justine (Montréal), 18/07/2008, ref: 2746

Study design

Double blind (participant, investigator, caregiver, outcome assessor, data analyst), randomised parallel trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Critically ill patients requiring red cell transfusions and having a probability of 28-day all-cause mortality exceeding 25%

Interventions

Experimental:

Transfusions of red cells stored less than 8 days issued by the local blood bank. This will be applied up to discharge from the hospital or step-down unit (not more than 90 days post-randomisation).

Control:

Transfusions of standard issue red cells (storage 2 to 42 days).

Intervention Type

Other

Primary outcome(s)

90-day all cause mortality

Key secondary outcome(s)

1. Other mortality rates and survival times as measured at ICU discharge, hospital discharge, 28 days and 6 months post-discharge
2. Number of cases of multiple organ dysfunction syndrome (MODS), highest number of organ failures per patient, MODS score and time to development of MODS as measured while in the ICU
3. Serious nosocomial infections including:
 - 3.1. Nosocomial pneumonia

- 3.2. Deep tissue infections (e.g. peritonitis, mediastinitis)
- 3.3. Bacteraemia from organisms not considered normal skin flora and judged important enough to treat by the attending team, as measured while in the ICU
4. Adverse events and transfusion reactions as measured while in ICU
5. Length of stay (ICU and hospital)
6. Length of time requiring respiratory, haemodynamic and renal support as measured while in ICU

Completion date

01/04/2013

Eligibility

Key inclusion criteria

Patients who:

1. Have had a request for a first red cell unit transfusion in the Intensive Care Unit (ICU), and
2. Have an anticipated length of invasive and/or non-invasive continuous positive airway pressure (CPAP) or bi-level positive airway pressure (BIPAP) mechanical ventilation of at least 48 hours once enrolled, as estimated by the attending physician

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Investigators and research assistants will exclude patients:

1. Who are less than 16 years of age
2. Who were previously enrolled in the ABLE study
3. Who have already been transfused with red cells during the current hospitalisation
4. Who have an obvious terminal illness documented in the medical record with a life expectancy of less than 3 months
5. Who have undergone routine cardiac surgical care
6. Where a decision to withdraw/withhold some critical care had been made
7. Who are obviously brain dead

Investigators, research assistants and blood bank personnel will also exclude patients:

8. When there are no red cells with a storage time of 7 days or less available in the blood bank that cannot be transported from the blood supplier
9. Who require more than 1 unit of uncross-matched red cells
10. With a known objection to blood transfusions
11. With autologous blood donations
12. Who pose difficulties in securing blood products (rare blood groups), and who are difficult to match

Date of first enrolment

01/12/2008

Date of final enrolment

01/04/2013

Locations

Countries of recruitment

Canada

Study participating centre**Hôpital Sainte-Justine**

Montreal

Canada

H3T 1C5

Sponsor information

Organisation

Sainte-Justine Hospital Research Centre (Centre de recherche du CHU Sainte-Justine) (Canada)

ROR

<https://ror.org/01gv74p78>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-90648)

Alternative Name(s)

Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/04/2015		Yes	No