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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
22/08/2008		[] Protocol		
Registration date	Overall study status	Statistical analysis plan		
22/08/2008	Completed	[X] Results		
Last Edited 15/04/2015	Condition category Signs and Symptoms	Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s) Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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

Secondary study design Randomised parallel 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

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 measure

90-day all cause mortality

Secondary outcome measures

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

Overall study start date

01/12/2008

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

Age group

Adult

Sex Both

Target number of participants

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)

Sponsor details

2510

3175 Côte Sainte-Catherine Montreal, Quebec Canada H3T 1C5

Sponsor type Hospital/treatment centre

Website http://www.recherche-sainte-justine.qc.ca

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, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR, IRSC

Funding Body Type Government organisation

Funding Body Subtype National government

Location 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	09/04/2015		Yes	No