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

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

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

2510

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

3175 Côte Sainte-Catherine
Montreal, Quebec
Canada
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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