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Effects of transfusing fresh versus standard-issue red cells on in-hospital mortality

Submission date 04/08/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 11/01/2011	**Overall study status** Completed	
Last Edited 24/08/2012	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Nancy Heddle

Contact details
McMaster Transfusion Research Program
HSC-3H50
1200 Main St West
Hamilton
Canada
L8N 3Z5
+1 905 52591040 ext 22126
heddlen@mcmaster.ca

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Effects of transfusing fresh versus standard-issue red cells on in-hospital mortality: a pilot randomised controlled trial using a pragmatic approach

Acronym
INFORM

Study objectives
Hundreds of thousands of Canadians receive a red cell transfusion each year. Current methods of blood inventory management are to issue the oldest blood first to limit outdating. However, data from experimental and observational studies suggest that red cells stored for longer periods might lead to adverse outcomes, including an increase in mortality. The only way to answer this question is to undertake a randomised controlled trial (RCT). If such a trial showed a statistically significant and clinically important improvement in mortality with freshest available versus standard issue red cells, it is likely to lead to major changes in the management of red cell inventories and storage methods to increase the use of fresher red cells. Such a large pragmatic trial is complex; hence before initiating a large trial it is important to work out logistics and show feasibility. Our proposed pilot study will provide crucial information for the design of a large RCT that will yield reliable and precise estimates of the effect of freshest available versus standard-issue red cells on in-hospital mortality.

Further reading:
Duration of red cell storage before transfusion and in-hospital mortality. Eikelboom JW, Cook RJ, Liu Y, Heddle NM. Am Heart J. 2010 May;159(5):737-743.e1.
http://www.ncbi.nlm.nih.gov/pubmed/20435180

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Research Ethics Board at Hamilton Health Sciences approved on the 20th April 2010 (ref: 10-196)

Study design
Single centre pilot pragmatic double blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Red cell blood transfusion

Interventions
Patients requiring red cell transfusion will be randomised to one of the following conditions:
1. Experimental transfusion is freshest available red cells
2. Control is standard issue red cells (oldest product in stock)

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
Feasibility of randomising consecutive patients requiring blood transfusion: we anticipate that early in the study the failure rate may be higher due to the learning curve associated with the randomisation process; hence, the feasibility failure rate will be assessed on the data from the final 3 months of the 6 months pilot. This outcome will be monitored weekly with changes being implemented to prevent failures from occurring if possible. This is vital information in determining the feasibility of the larger RCT.

Key secondary outcome(s))
1. Impact on inventory and red cell outdating rate
2. Contrast in the age of fresh and standard-issue red cells
3. Ability to provide timely reports to monitor inventory levels
4. Outdating and age overlap

The frequency of in-hospital mortality will also be documented but used only to estimate the sample size for expanding the study if feasibility is demonstrated.

Completion date
01/12/2010

Eligibility

Key inclusion criteria
1. Patients who are admitted to Hamilton General Hospital
2. Destined to receive a red cell transfusion
3. Either sex, no age restrictions

The REB has approved that this study to be done with waived consent as it meets the 5 requirements for waived consent identified by the Tri Council Policy. However, to meet all requirements of this policy, patients will be informed that this study is taking place and will be given a summary of the study.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. Patients who have a particular requirement for fresh red cells (e.g., sickle cell disease, transfusion dependent thalassemia, fresh cells requested by physician)

2. Are to receive pre-planned directed or autologous donations
3. Massive transfusion anticipated
4. Being transfused as an outpatient

Date of first enrolment
01/01/2010

Date of final enrolment
01/12/2010

Locations

Countries of recruitment
Canada

Study participating centre
McMaster Transfusion Research Program
Hamilton
Canada
L8N 3Z5

Sponsor information

Organisation
McMaster University (Canada)

ROR
https://ror.org/02fa3aq29

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: 221072)

Funder Name
Canadian Blood Services (Canada)

Alternative Name(s)
Société canadienne du sang, Canadian Blood Services - Ontario, lifelineontario, CBS

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

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	01/06/2012		Yes	No