

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

Submission date 04/08/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 11/01/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 24/08/2012	Condition category Surgery	<input type="checkbox"/> Individual participant data

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
hedden@mcmaster.ca

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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, Hedde 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet.

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 measure

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.

Secondary outcome measures

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.

Overall study start date

01/01/2010

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

Age group

Other

Sex

Both

Target number of participants

1320

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)

Sponsor details

1200 Main Street West
Hamilton, Ontario
Canada
L8N 3Z5

Sponsor type

University/education

Website

<http://www.mcmaster.ca/>

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, CBS

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

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	01/06/2012		Yes	No