ISRCTN08118744 https://doi.org/10.1186/ISRCTN08118744

Informing fresh versus standard Issue red cell management

Submission date
23/11/2011

Recruitment status
No longer recruiting

Registration date
16/02/2012

Overall study status
Completed

Last Edited
01/03/2019

Condition category
Haematological Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Transfusion of red blood cells is life-saving, but recent data suggests that transfusion of stored blood may also cause some harm. Transfusion of red blood cells stored for up to 42 days is standard medical practice. Recent studies have suggested the changes that develop during red blood cell storage might contribute to increased risk in some patients, but the results have generated significant controversy. In order to resolve the controversy, several studies are currently underway in very specific patient populations (critical care patients, patients undergoing cardiac surgery) comparing very fresh blood (less than 8 to 10 days of storage, with standard issue blood. This study will include all hospital patients receiving transfusion and does not use a specific storage age to define fresh blood; hence, it will provide information that will apply to all transfused patients. This study aims to determine the effect on in-hospital death rates of transfusing the freshest available blood compared with standard-issue blood.

Who can participate?
All adults (18 years of age or older) patients admitted to the hospital who will receive a transfusion during their stay are potentially eligible for the study.

What does this study involve?
The participant will not be contacted during this study. The decision to transfuse is determined by the patient's doctor. Once the ward orders the blood, the Transfusion Medicine Service will randomly allocate the patient to receive either the freshest available or standard-issue blood. The patient's data will be collected electronically. An information brochure will be distributed to the patient so they are made aware of the study.

What are the possible benefits and risks of participating?
As of yet, there are no direct known benefits for the participating patients. Future societal benefits may occur from this study depending on the study findings. There are no added risks of participating in this study. The decision to transfuse a patient happens independently of the study.

Where is the study run from?
The study is run from the McMaster Transfusion Medicine Program at McMaster University in

Hamilton, Canada. Patients are recruited from Hamilton General Hospital (Canada), Juravinski Hospital (Canada), Flinders Medical Centre (Australia), St Joseph's Healthcare in Hamilton (Canada) and the Cleveland Clinic (USA).

When is the study starting and how long is it expected to run for?
January 2012 to November 2015

Who is funding the study?
Canadian Institutes of Health Research (CIHR) (Canada)

Who is the main contact?
Rebecca Barty
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Sept122011

Study information

Scientific Title
INforming Fresh versus Old Red cell Management (INFORM): a large simple phase III randomized controlled trial

Acronym
INFORM

Study objectives
The freshest available compared with standard-issue blood reduces mortality.

Pilot study registered under ISRCTN38768001.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Hamilton Health Sciences/Faculty of Health Sciences, Research Ethics Board, 16/08/2011
2. Southern Adelaide Clinical Human Research Ethics Committee, 15/08/2011
3. Cleveland Clinic, Institutional Review Board, 11/06/2012
4. St Joseph's Healthcare, Research Ethics Board, 17/05/2012

Study design
Multi-centre international randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

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

Interventions
Patients requiring red blood cell transfusion will be randomized to one of the following conditions:
1. Freshest available red blood cells (experiment arm)
2. Standard-issue (oldest product compatible in stock) red blood cells available (control arm)
Both arms (experiment and control) are within standard care

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Intervention Type
Biological/Vaccine

Phase
Phase III

Primary outcome measure
In-hospital mortality

Secondary outcome measures
Time to event (death)

Overall study start date
16/01/2012

Completion date
20/11/2015

Eligibility

Key inclusion criteria
All adult patients (age >/= 18) will be included if:
1. Hospitalized at a participating centre (in-patient)
2. Undergoing a red cell transfusion

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
31,497

Key exclusion criteria
1. Specific requirement for fresh blood (e.g., sickle cell disease, transfuion-dependent thalassemia, fresh cells ordered by care provider)
2. Pre-planned directed or autologous donation
3. Request for un-crossmatched blood
4. Anticipated massive transfusion as communicated from clinical area

Date of first enrolment
02/04/2012

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
Australia

Canada

Israel

United States of America

Study participating centre
Hamilton General Hospital
Canada
-

Study participating centre
Juravinski Hospital
Canada
-

Study participating centre

Flinders Medical Centre
Australia
-

Study participating centre
St Joseph's Healthcare Hamilton
Canada
-

Study participating centre
Cleveland Clinic
United States of America
-

Study participating centre
Meir Medical Center
Israel
-

Sponsor information

Organisation
McMaster University (Canada)

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Sponsor type
University/education

Website
http://fhs.mcmaster.ca/mtrp/

ROR

https://ror.org/02fa3aq29

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada)

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
Investigators currently are preparing a study design manuscript.

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?
Protocol article	protocol	01/01/2016		Yes	No
Results article	results	17/11/2016		Yes	No
Other publications	secondary analysis	01/11/2017		Yes	No