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Age of Red blood cells In Premature Infants trial

Submission date 02/10/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 02/10/2006	**Overall study status** Completed	
Last Edited 16/10/2012	**Condition category** Pregnancy and Childbirth	

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
NCT00326924

Secondary identifying numbers
MCT-75527

Study information

Scientific Title
Age of Red blood cells In Premature Infants: a multicentre, two arm, randomised parallel trial

Acronym
ARIPI

Study objectives
The transfusion of red blood cells (RBCs) stored for less than or equal to seven days will decrease the incidence of a 90-day composite measure consisting of all-cause mortality and organ dysfunction including bronchopulmonary dysplasia, necrotising enterocolitis, intraventricular haemorrhage and retinopathy of prematurity in premature infants weighing less than or equal to 1250 grams.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Board of The Ottawa Hospital, Ottawa, Ontario (Canada) approved on the 14th June 2006.

Study design
Multicentre, two arm, randomised parallel trial with study participant, investigator, caregiver, outcome assessor and data analyst blinded

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Premature infants weighing less than 1250 g admitted to the neonatal intensive care unit

Interventions
Experimental Group: transfusion of fresh blood stored less than or equal to seven days. Control Group: standard practice (blood stored up to 35 days).

In all sites but Saskatoon, O-Rh negative RBCs will be divided into satellite units of between four and eight aliquots, and these aliquots will be removed from their satellite units as needed in order to reduce wastage. Dose as per standard care/duration: up to 90 days.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Composite outcome comprised of five major neonatal morbidities:
1. Necrotising enterocolitis
2. Retinopathy of prematurity
3. Bronchopulmonary dysplasia
4. Intraventricular hemorrhage
5. Mortality measured at 90 days

Secondary outcome measures
1. Nosocomial infection
2. Individual rates of the morbidities comprising the primary outcome:
2.1. Necrotising enterocolitis
2.2. Retinopathy of prematurity
2.3. Bronchopulmonary dysplasia
2.4. Intraventricular hemorrhage
2.5. Death

Tertiary outcomes will include:
1. Length of mechanical ventilation
2. Length of stay in the NICU
3. Both minor and major interventions received while in the NICU

Overall study start date
01/05/2006

Completion date
31/12/2009

Eligibility

Key inclusion criteria
1. Requirement of a second allogeneic RBC transfusion for the treatment of prematurity
2. Infant age 0 - 27 days, either sex
3. Less than 1250 grams birth weight
4. Admitted to the participating Neonatal Intensive Care Unit (NICU)
5. Parents or guardian have signed (proxy) informed consent

Participant type(s)
Patient

Age group
Neonate

Sex
Both

Target number of participants
450

Key exclusion criteria
1. Infants whose first transfusion was older than seven days
2. Infants already given a second RBC transfusion
3. Infants scheduled to undergo an exchange transfusion
4. Infants that will receive directed donations
5. Infants that have rare blood types or difficulty with cross-matching
6. Infants whose proxy has refused consent
7. Infants who are moribund upon admission to the NICU or not expected to survive due to a severe congenital anomaly

Date of first enrolment
01/05/2006

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Canada

Study participating centre
Clinical Epidemiology Program
Ontario
Canada
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Sponsor information

Organisation
Ottawa Hospital Research Institute (OHRI) (Canada) - formerly Ottawa Health Research Institute

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Sponsor type
Research organisation

Website
http://www.ohri.ca/

ROR
https://ror.org/03c62dg59

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-75527)

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?
Protocol article	protocol	01/01/2009		Yes	No
Results article	results	10/10/2012		Yes	No