

Age of Red blood cells In Premature Infants trial

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00326924

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Neonate

Sex

All

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

K1H 8L6

Sponsor information

Organisation

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

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

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	10/10/2012		Yes	No
Protocol article	protocol	01/01/2009		Yes	No