

# Age of Red blood cells In Premature Infants trial

<b>Submission date</b> 02/10/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 02/10/2006	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 16/10/2012	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Dean A Fergusson

**Contact details**  
Clinical Epidemiology Program  
Ottawa Hospital Research Institute  
501 Smyth Road, Box 201  
Ottawa  
Ontario  
Canada  
K1H 8L6  
+1 613 737 8480  
dafergusson@ohri.ca

## 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?
<a href="#">Results article</a>	results	10/10/2012		Yes	No
<a href="#">Protocol article</a>	protocol	01/01/2009		Yes	No