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A randomised controlled trial: two haemoglobin thresholds for transfusion in newborns less than 1000 g birth weight

Submission date	Recruitment status	[ ] Prospectively registered
26/07/2007	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
26/07/2007	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
08/06/2022	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

ClinicalTrials.gov (NCT)
NCT00182390

Protocol serial number
MCT-41549 (follow-up trial PINTOS [started in 2002]: MCT-58455)

Study information

Scientific Title
A randomised controlled trial: two haemoglobin thresholds for transfusion in newborns less than 1000 g birth weight

Acronym
PINT (Preterms In Need of Transfusion)

Study objectives
A high haemoglobin threshold for transfusion in Extremely Low Birth Weight (ELBW) infants is associated with a lower rate of survival without severe morbidity (defined as one or more of retinopathy of prematurity, bronchopulmonary dysplasia, or periventricular leukomalacia /ventriculomegaly).

PINTOS: Neurodevelopmental outcome of extremely low birth weight infants randomised to high or low haemoglobin triggers for blood transfusion -
A follow up study was added to this trial in 2002 by Dr Whyte (all details pertaining to the follow up will be headed with the title 'PINTOS'). The hypothesis for this follow-up was that a low haemoglobin threshold as compared to a high haemoglobin threshold for transfusion in ELBW infants is associated with a lower rate of the combined outcome of death or, in survivors, the presence of cerebral palsy, cognitive delay, blindness or deafness at 18 - 21 months follow-up.

Please note that this trial was intially submitted for an ISRCTN in September 2005.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was gained from the Research Ethics Boards:
For PINT: of McMaster University (Canada) on the 20th November 2002 (ref: #00-255).
For PINTOS: of IWK Health Centre, Halifax, NS, Canada, 14 July 2004 (ref: #2052).

Study design
Multicentre, international, therapeutic management strategy randomised parallel, two arm trial, with outcome assessor and data analyst blinded.

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anaemia of prematurity

Interventions
Transfusion at low haemoglobin threshold; blood transfusion with 15 ml/kg packed erythrocytes when the haemoglobin level, taken from capillary or central sites, falls to or below the following levels:

Group 1: Haemoglobin Threshold for Transfusion -
1. Week 1 (postnatal age):
1.1. Capillary sampling site: respiratory support: 115 g/l; not requiring respiratory support: 100 g/l
1.2. Central sampling site: respiratory support: 104 g/l; not requiring respiratory support: 90 g/l
2. Week 2 (postnatal age):
2.1. Capillary sampling site: respiratory support: 100 g/l; not requiring respiratory support: 85 g/l
2.2. Central sampling site: respiratory support: 90 g/l; not requiring respiratory support: 77 g/l
3. Greater than or equal to week 3 (postnatal age):
3.1. Capillary sampling site: respiratory support: 85 g/l; not requiring respiratory support: 75 g/l
3.2. Central sampling site: respiratory support: 77 g/l; not requiring respiratory support: 68 g/l

Group 2: Haemoglobin Threshold for Transfusion -
1. Week 1 (postnatal age):
1.1. Capillary sampling site: respiratory support: 135 g/l; not requiring respiratory support: 120 g/l
1.2. Central sampling site: respiratory support: 122 g/l; not requiring respiratory support: 109 g/l
2. Week 2 (postnatal age):
2.1. Capillary sampling site: respiratory support: 120 g/l; not requiring respiratory support: 100 g/l
2.2. Central sampling site: respiratory support: 109 g/l; not requiring respiratory support: 90 g/l
3. Greater than or equal to week 3 (postnatal age):
3.1. Capillary sampling site: respiratory support: 100 g/l; not requiring respiratory support: 85 g/l
3.2. Central sampling site: respiratory support: 90 g/l; not requiring respiratory support: 77 g/l

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Sponsor for PINTOS trial:
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Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
Survival to tertiary hospital discharge without severe morbidity (one or all of bronchopulmonary dysplasia, retinopathy of prematurity Grade 3 - 4, periventricular leukomalacia/ventriculomegaly present on ultra-sound scans) at corrected age 40 weeks.

PINTOS:
Composite outcome of death or the presence of cerebral palsy, cognitive delay, blindness or deafness measured at or during 24 months.

Key secondary outcome(s))
1. Growth in weight and head circumference
2. Time to extubation, by discharge from hospital
3. Time on oxygen, by discharge from hospital
4. Length of hospital stay until discharge home
5. Incidences of necrotising enterocolitis
6. Apnoea requiring treatment
7. Number of infections
8. Use of post-natal steroids
9. Intraventricular haemorrhage Grade 4 or with hydrocephalus
10. Mean levels of haemoglobin
11. Number of transfusions
12. Number of donor exposures

Time point of measurement: at discharge from hospital or at corrected age of 40 weeks.

PINTOS:
1. Vineland Communication score
2. Vineland Daily Living score
3. Vineland Socialisation score
4. Vineland Motor Skills score
5. Gross Motor Function Classification System Levels
6. Weight
7. Length
8. Head Circumference
9. Haemoglobin
10. Haematocrit

11. Mean Corpuscular Haemoglobin
12. Mean Cell Volume
13. Ferritin

Time point of measurement: 18 - 21 months corrected gestational age.

Completion date
15/09/2005

Eligibility

Key inclusion criteria
1. Infants of birth weight less than 1000 g, either sex
2. Postnatal age less than 48 hours
3. No transfusion beyond first six hours of life
4. Estimated gestational age of 30 completed weeks or less

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Key exclusion criteria
1. Infant considered non-viable by attending physician
2. Infant has cyanotic congenital heart disease
3. Infant's parents known to be opposed to blood transfusion
4. Either parent has haemoglobinopathies or congenital anaemias
5. Infant has haemolytic disease
6. Infant has severe acute haemorrhage, severe shock, severe sepsis with coagulopathy or requires peri-operative transfusion
7. Prior treatment with or intention to treat with erythropoietin

Date of first enrolment
04/02/2001

Date of final enrolment
15/09/2005

Locations

Countries of recruitment
Australia

Canada

United States of America

Study participating centre
Room 3N11F
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Sponsor information

Organisation
McMaster University (Canada)

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: PINT: MCT-41549/PINTOS: MCT-58455)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		01/09/2006		Yes	No
Other publications	follow up study	01/01/2009	08/06/2022	Yes	No