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Transfusion Requirements in Paediatric Intensive Care Unit

Submission date	Recruitment status	[_] Prospectively registered
27/06/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/07/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/11/2013	Haematological Disorders	

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

Secondary identifying numbers
CIHR-RCT 130770

Study information

Scientific Title
Transfusion Requirements in Paediatric Intensive Care Unit: a multicentre randomised controlled non-inferiority clinical trial

Acronym
TRIPICU

Study objectives
A restrictive transfusion strategy, using pre-storage leukocyte reduced packed red blood cell units, would not be inferior to a liberal strategy in its effects on multiple organ dysfunction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
IRB approval was gained from the Comité d'éthique à la recherche for all participating sites prior to participant recruitment.

Study design
Multicentre randomised controlled non-inferiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

Interventions
Giving more or less red blood cell transfusion.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Number of patients who developed new or progressive multiple organ dysfunction syndrome.

Secondary outcome measures
1. Descriptors of severity of cases of multiple organ dysfunction syndrome (Paediatric Logistic Organ Dysfunction [PELOD] score, maximal number of organ dysfunctions)
2. Mortality (28-day, ICU and hospital mortality rates)
3. Nosocomial infections
4. Length of mechanical ventilation
5. Length of ICU stay and of total hospital stay
6. Adverse events
7. Transfusion reactions

Overall study start date
26/11/2001

Completion date
28/08/2005

Eligibility

Key inclusion criteria
1. Stable critically ill children with haemoglobin concentrations below 9.5/dL g within seven days of admission to intensive care unit
2. Aged greater than or equal to 3 days or less than or equal to 14 years old, either sex

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Days

Upper age limit
14 Years

Sex
Both

Target number of participants
626

Key exclusion criteria
1. Post-conception age less than 40 weeks at the time of randomisation
2. Present age less than three days after birth (at term) or less than 14 years old
3. Weight less than 3 kg at the time of randomisation
4. Previous enrolment of a patient in this trial
5. Never discharged home following admission to a neonatalogy intensive care unit
6. Pregnant
7. Post-operative care of a neonatal cardiac surgery who is less than 28 days of age when the surgery occurs

8. Post-operative care of a planned surgery for a cyanotic cardiopathy, unless the cardiopathy was corrected and the patients is older than 28 days of age
9. The patient has an uncorrected cyanotic cardiopathy
10. Haemolytic anaemia (example: sickle cell disease, haemolytic uraemic syndrome)
11. Inability to receive blood for transfusion (e.g. presence of multiple antibodies, Jehovah Witness or other cultural/religious ideology)
12. Hypoxaemia (saturation of oxyhaemoglobin [SpO2] less than or equal to 90% measured using pulse oxymeter) that persists despite a fraction of inspired oxygen (FiO2) of more than or equal to 60% (his criteria will be adopted in the presence of permissive hypoxaemia and of congenital cardiopathy - cyanotic and non-cyanotic)
13. Not considered volume resuscitated by the attending intensivist
14. The blood pressure of the patient is not under control or the patient is not haemodynamically stable
15. Present an acute clinically significant active blood loss at the time of enrolment
16. Severe thrombocytopenia (platelet count less than 20.0 x 10^9/L or 20 000/mm^3)
17. Brain death or suspected brain death
18. Blood exchange-transfusion (manual or automated)
19. Plasmapheresis
20. Haemofiltration, if priming is done with blood
21. Extracorporeal membrane oxygenation (ECMO)
22. Decision taken to withhold or to withdraw critical care
23. Moribund and not expected to survive more than 24 hours (as judged by the attending intensivist)
24. Lack of commitment from the attending staff to continue active treatment of the patient
25. Expected to stay less than 24 hours in the Paediatric Intensive Care Unit (PICU) (as judged by the attending intensivist)
26. Refusal of consent by patient and/or parent
27. Refusal of consent by physician
28. Enrolment in another interventional study that could interfere with the TRIPICU trial

Date of first enrolment
26/11/2001

Date of final enrolment
28/08/2005

Locations

Countries of recruitment
Belgium

Canada

United Kingdom

United States of America

Study participating centre

3175 Cote Sainte-Catherine
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Sponsor information

Organisation
Sainte-Justine Hospital - Research Centre (Canada)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/01gv74p78

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: 130770)

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?
Results article	results	19/04/2007		Yes	No
Results article	results	01/02/2010		Yes	No