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Transfusion Requirements in Paediatric Intensive Care Unit

Submission date
27/06/2004

Recruitment status
No longer recruiting

Registration date
04/07/2005

Overall study status
Completed

Last Edited
15/11/2013

Condition category
Haematological Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jacques Lacroix

Contact details
3175 Cote Sainte-Catherine
Montréal
Canada
H3T 1C5
+1 514 7392589 or 3454931ext5556
j_lacroix@videotron.ca

Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
Number of patients who developed new or progressive multiple organ dysfunction syndrome.

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 days

Upper age limit
14 years

Sex
All

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
United Kingdom

Belgium

Canada

United States of America

Study participating centre
3175 Cote Sainte-Catherine
Montréal
Canada
H3T 1C5

Sponsor information

Organisation
Sainte-Justine Hospital - Research Centre (Canada)

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

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