Platelet transfusions in neonates

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Determination of non-inferiority of volume-reduced platelet concentrates compared to plasma platelet concentrate in terms of recovery. To assess safety (bleeding and thrombotic complications, and adverse transfusion reactions) and transfusion...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Platelet disorders
Study type	Interventional

Summary

ID

NL-OMON36168

Source
ToetsingOnline

Brief title
PLANET study

Condition

- Platelet disorders

Synonym
thrombocytopenia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: neonate, platelet transfusion, thrombocytopenia, volume reduction

Outcome measures

Primary outcome

To assess recovery, estimated by platelet transfusion increment at 1 hour and

24 hour.

Secondary outcome

1. To assess the safety (bleeding / thrombotic complications / adverse

transfusion reactions).

2. To assess the transfusion interval, estimated as interval to next

transfusion.

3. To assess the donor exposure.

Study description

Background summary

Platelet concentrates are used to prevent and treat bleeding complications. For neonates, the standard platelet transfusion product is transfused at a dose of 10 (-20) ml per kg body weight. Volume overload caused by the need for intravenous medication, blood products and parenteral nutrition, however, is a serious clinical problem in neonates treated on the Neonatal Intensive Care Unit (NICU). In these patients, the clinical transfusion requirements compete with the risks associated with the volume overload. We hypothesize that by using volume reduced platelet concentrates we can safely achieve comparable platelet transfusion increments as with the standard platelet concentrate.

Study objective

Determination of non-inferiority of volume-reduced platelet concentrates compared to plasma platelet concentrate in terms of recovery. To assess safety (bleeding and thrombotic complications, and adverse transfusion reactions) and transfusion requirement.

Study design

Randomized clinical trial.

Intervention

Randomization of patients between platelet transfusion support with standard plasma aphaeresis platelet concentrate: 10 * 10 9 platelets/kg body weight in a volume of 10 mL/kg body weight (Arm A), or volume-reduced aphaeresis platelet concentrates: 20 * 10 9 platelets/kg body weight in a volume of 2 mL/kg body weight (Arm B).

Study burden and risks

Burden: The monitoring of platelet count increments 1 hour and 24 hour after platelet transfusion is part of regular patient care. Before and after transfusion ultrasounds of the venous catheters to detect any new thrombosis will be made.
Risk: The volume-reduced product is the standard platelet concentrate for transfusion in neonates in the NICU of the LUMC, Leiden. A recent retrospective study comparing the platelet transfusion practices between both centres did not show any risk associated with the volume-reduced blood product.
Group relatedness: Circulatory overload is a common clinical problem on the NICU.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Neonates, <28 days postnatal age, admitted to the neonatal or pediatric intensive care (NICU/PICU) with thrombocytopenia that require a platelet transfusion according to the clinical guidelines.
- Written informed consent by parent(s) or caregiver(s).

Exclusion criteria

- Neonatal allo-immune thrombocytopenia (NIATP)
- Maternal ITP
- Therapeutic platelet transfusion during surgery
- Platelet transfusion during red blood cell exchange.
- Platelet transfusion during extracorporal membrane oxygenation (ECMO).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-03-2012
Enrollment:	76
Type:	Actual

Ethics review

Approved WMO Date:	16-09-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL37198.078.11