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A randomised controlled trial to compare two different platelet count thresholds for prophylactic platelet transfusion to preterm neonates

Submission date
29/09/2011

Recruitment status
No longer recruiting

Registration date
29/09/2011

Overall study status
Completed

Last Edited
24/02/2023

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Platelets are the cells that help the blood to clot. Platelet counts may sometimes fall to low levels in about 5% of babies in the neonatal unit, usually when babies are unwell. Platelet transfusions are like blood transfusions only the bag contains platelets and no red blood cells. Platelet transfusions are given to babies with low platelets and signs of bleeding, but we do not know when it is best to give platelet transfusions to babies with low platelets and no signs of bleeding. Although platelet transfusions will help clotting they may also carry some risks. The aim of this study is to understand better when to give transfusions of platelets to babies with low platelet counts. There are no studies to tell us what is best for the babies. We would like to find out which platelet levels we should transfuse at in babies with low platelets and no evidence of bleeding. We will therefore compare outcomes at two different platelet levels.

Who can participate?
Babies who are born below 34 weeks Corrected Gestational Age (CGA), have a platelet count below 100 and are being cared for in one of the participating hospitals.

What does the study involve?
Clinical staff will continue to check daily platelet counts to see whether the baby needs a platelet transfusion. If the babys platelet count drops below the level of 50, then it will be placed at random into one of two groups. Group 1 babies will receive a platelet transfusion whenever their platelet count drops below 50. Group 2 babies will receive a platelet transfusion whenever their platelet count drops below 25. This random allocation is made by a computer programme. Randomly placing babies in the groups ensures that every baby has an equal chance of being in either group 1 or group 2. Once the baby is enrolled in the study relevant information will be collected about the baby every day for 14 days. This will involve checking for any signs of bleeding. After 14 days, information for the study will be collected on a weekly basis until the baby is discharged home. This information will be collected by speaking to the nursing staff and from the case notes. If the care of a baby is provided in different hospitals, then the doctors and

nurses in each hospital will continue to complete the weekly information collection until discharge home. No additional blood tests will be carried out solely for the purposes of the study. The study will not interfere with the medical or nursing care a baby will receive during this time. Being in this study will not stop the doctors giving platelets to a baby when it is considered appropriate for their care. All babies in the study will be followed up at 2 years of age to assess their development by using a standard form.

What are the possible benefits and risks of participating?
We do not know if a particular baby will benefit from taking part in the study; some babies may benefit from receiving fewer or more transfusions, but we do not know. We hope that the information from this study will help improve the future care of very premature babies. The information we get from this study will help us to improve the way we use platelet transfusions and guide us to recommend to others which platelet count level should be used to give platelet transfusions to very premature babies. Currently there is no clear evidence when to give platelet transfusions to babies who have a low platelet count but are not bleeding. It is possible that some babies who do not receive platelet transfusion when their platelet counts are low may have bleeding. On the other hand giving more transfusions of platelets also carries a small risk of causing harm, as for any blood transfusion. These risks include bacterial and viral infections, transfusion reactions and the need for more procedures for administering platelets (such as insertion of intravenous cannula). All babies in the study will be carefully monitored by research and clinical staff.

Where is the study run from?
The study is being run by the NHS Blood and Transplant Clinical Trials Unit (NHSBT CTU). Neonatal Intensive Care Units in the UK, Ireland and Netherlands are participating.

When is the study starting and how long is it expected to run for?
June 2011 to August 2020

Who is funding the study?
The study is being organised and funded by the NHS Blood and Transplant Clinical Trials Unit (NHSBT CTU).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Protocol serial number
10305

Study information

Scientific Title
A randomised controlled trial to compare two different platelet count thresholds for prophylactic platelet transfusion to preterm neonates

Acronym
PlaNet2

Study objectives
Platelets are the cells that help blood to clot and so help the body to stop bleeding. Platelets, like red cells, are given by transfusion. There is a wide variation in practice about when to give platelets to babies with low platelet counts if they are not bleeding. It is not clear whether these transfusions are really always necessary and we also know that all transfusions carry a degree of risk. We want to find out what platelet count is appropriate and safe to give platelet transfusions to preterm babies who are not bleeding. We have previously completed and published a cross-sectional study of neonates with very low platelet count (PlaNet-1) to examine the frequency and timing of bleeding and the use of platelet transfusions. The proposed randomised trial will compare two different platelet count thresholds for transfusion.

This study will take place in multiple hospitals in the UK and approximately 600 babies will participate. The population to be studied is preterm babies of <34 weeks gestational age at birth admitted to UK Level 2 or 3 neonatal intensive care units (as defined by the British Association of Perinatal Medicine; 2001). Outcomes will be documented daily in hospital and evidence of bleeding will be carefully recorded in all neonates using a bleeding assessment tool adapted for neonates. The main endpoint for this trial is a combined outcome of all-cause mortality and new major bleeding up to and including day 28 after randomisation. Other outcomes include mortality and new major bleeds from randomisation to discharge home; the rate and timing of minor, moderate and major bleeding derived from the bleeding assessment tool from randomisation to day 28 post randomisation; and neurodevelopmental outcome as assessed by the Health Status Questionnaire at 2 years. The study is funded by NHSBT.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 3 Research Ethics Committee, original approval granted: 05/11/2010, substantial amendment: 12/05/2011, 10/H0306/61

Study design
Randomised; Interventional; Design type: Not specified

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Paediatrics

Interventions
Trial intervention, Counselling and procedures for obtaining parental consent for the study will commence when the neonate s platelet counts fall below 100 x109/L.

Neonates for whom parental consent has been obtained will be enrolled into the study when their platelet count has fallen below 50 x109/L and randomised into one of two arms to receive prophylactic platelet transfusions triggered by either a platelet count below 25 x109/L or below 50 x109/L.

Consented neonates with platelet counts below 50 x109/L w; Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
The proportion of patients who either die or experience a major bleed

Key secondary outcome(s))
Proportion of patients surviving to go home following a major bleed, censoring at discharge

Completion date
31/08/2020

Eligibility

Key inclusion criteria
1. Written informed consent obtained
2. Admission to a participating neonatal intensive care unit (NICU) (includes postnatal transfers)
3. <34 weeks gestational age at birth
4. A platelet count of < 50x10^9/L
5. Cranial ultrasound scan must have been undertaken less than 6 hours prior to randomisation in order to rule out recent major intraventricular hemorrhage (IVH)

IVH defined as any haemorrhage (H1, H2 or H3) with ventricular dilatation (V1) (Grade 3 Papile grading, (Papile et al 1978) or any haemorrhage (H1,H2,H3) with parenchymal involvement (P1, P2 or P3) (Grade 4 Papile grading,) within the past 72 hours. If a cranial ultrasound scan (which

typically takes a few minutes to complete) has not been undertaken less than 6 hours prior to randomisation it must be performed before the baby can be randomised.

Target Gender: Male & Female; Upper Age Limit 34 weeks ; Lower Age Limit 23 weeks

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Neonate

Sex
All

Total final enrolment
660

Key exclusion criteria
1. Major/lifethreatening congenital malformations (e.g. chromosomal anomalies, Fanconis anaemia, Thrombocytopenia Absent Radius syndrome)
2. Recent major IVH within the last 72 hours i.e. any haemorrhage (H1, H2 or H3) with ventricular dilatation (V1) (Grade
3. Papile grading, or any haemorrhage (H1, H2 or H3) with parenchymal involvement (P1, P2 or P3) (Grade 4 Papile grading)
4. All fetal intracranial haemorrhages excluding subependymal haemorrhage from any antenatal ultrasound scan
5. Known immune thrombocytopenia or family history of alloimmune thrombocytopenia or maternal antiplatelet antibodies or maternal idiopathic thrombocytopenic purpura
6. Neonates judged by the attending neonatologist to be unlikely to survive more than a few hours at the time of proposed randomisation
7. Neonates who were not given parenteral Vitamin K after birth

Date of first enrolment
01/06/2011

Date of final enrolment
17/08/2017

Locations

Countries of recruitment
United Kingdom

England

Ireland

Netherlands

Study participating centre
Cambridge University Hospitals NHS Foundation Trust
Cambridge
United Kingdom
CB2 0SW

Sponsor information

Organisation
National Blood Service (UK)

ROR
https://ror.org/0227qpa16

Funder(s)

Funder type
Government

Funder Name
National Research & Development Committee (UK)

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	results	17/01/2019		Yes	No
Results article	Two-year follow-up data	21/02/2023	24/02/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes