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Platelet Responsiveness and Outcome from Platelet Transfusion (PROmPT)

Submission date	Recruitment status	[ ] Prospectively registered
19/11/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/11/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/06/2016	Cancer	[ ] Record updated in last year

Plain English summary of protocol
http://www.cancerresearchuk.org/cancer-help/trials/a-study-looking-at-differences-in-platelets-and-how-well-they-work-prompt

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

11139

Study information

Scientific Title
Platelet Responsiveness and Outcome from Platelet Transfusion - does inherent variation in donor platelet function affect the clinical efficacy of apheresis platelets? A randomised double blind single centre trial.

Acronym
PROmPT

Study objectives
The PROMPT study is a randomised double blind controlled trial. We want to determine whether the activity/responsiveness of platelets (as defined by in vitro responsiveness to agonists) given to stable patients with thrombocytopenia (low platelet numbers), affects patients platelet counts following transfusion. We are also interested in investigating whether there is any change in the patients bleeding in the days after the platelet transfusion has been given. We will do this by randomising patients to receive a single platelet transfusion of either high or low responsiveness and monitoring the outcomes. We will also collect some non-randomised (but still blinded) data on trial units. In addition we will collect the outcome data from some enrolled patients who are given a non-study transfusion of platelets so that we can compare the results to the study transfusions.

Platelets are vitally important cells for blood clotting and, as with many human characteristics (such as height, weight etc), there is a normal range of their functional activity as demonstrated by their responsiveness to agonists. Agonists are biological molecules which switch on platelets. This means that the majority of the population have platelets of medium responsiveness; however there is a small percentage of normal individuals who have very active (high responsiveness) or very inactive (low responsiveness) platelets.

It is not fully understood what effect differences in platelet activity levels would have for a patient when they are given a platelet transfusion. It is possible that following transfusion very active platelets are more rapidly removed from the circulation.

More details can be found at: http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=11139

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hertfordshire Research Ethics Committee, 20 July 2011 ref: 11/EE/0227

Study design
Randomised interventional trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
National Cancer Research Network, Blood

Interventions
Patients will be randomised to a single unit from either a low or high responding donor. The responsiveness of the donor's platelets in vitro to agonists (molecules which "switch on" platelets) has been previously determined and has been shown to be reproducible. In addition up to 30 patients will also be monitored for a non-trial (control) transfusion to determine usual outcome for this patient group.

Duration of follow-up is 5 days or until the next platelet transfusion (whichever is sooner).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Count increment at 1 hour; measured as difference between pre and 1 hour post transfusion count. Corrected for dose and BSA.

Secondary outcome measures
1. 24 hour count increment measured as difference between pre and 24 hour count
2. Bleeding Score - both patient and clinician assessed
3. Red cell transfusion measured as number of red cell units transfused
4. Time to next platelet transfusion measured as number of days to next transfusion

Overall study start date
03/10/2011

Completion date
03/10/2013

Eligibility

Key inclusion criteria
1. Age 16 years or older
2. Stable Haematology/Oncology Patients at Addenbrookes Hospital

3. Thrombocytopenia secondary to bone marrow failure, requiring platelet transfusions according to local and British Committee for Standards in Haematology (BCSH) Guidelines
4. Patients who, if peripheral venous access for blood sampling is required, have adequate access and will consent to their blood being taken in this way
5. Patients able to give written informed consent
6. Male or female

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
UK Sample Size: 130; Description: 100 Trial units and 30 control units.

Key exclusion criteria
1. Inherited or acquired clotting disorders
2. Inherited or acquired platelet function disorders
3. Current Acute Promyelocytic Leukaemia
4. Previously documented WHO Grade 4 bleeding (debilitating blood loss)
5. Palpable Splenomegaly
6. Immunological refractoriness to platelet transfusion
7. Require HLA or HPA matched platelets
8. Pregnant or lactating women
9. Other active malignancy in past 5 years

Date of first enrolment
03/10/2011

Date of final enrolment
03/10/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
NHS Blood and Transplant (NHSBT)
Cambridge
United Kingdom
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Sponsor information

Organisation
NHS Blood and Transplant [NHSBT] (UK)

Sponsor details
Research & Development
National R&D Office
500 North Bristol Park
Northway
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United Kingdom
BS34 7QH

Sponsor type
Hospital/treatment centre

Website
http://www.nhsbt.nhs.uk/

ROR
https://ror.org/0227qpa16

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
NHS Blood and Transplant [NHSBT] (UK)

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