

Platelet Responsiveness and Outcome from Platelet Transfusion (PROmPT)

Submission date 19/11/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 19/11/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 22/06/2016	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

CB2 2PT

Sponsor information

Organisation

NHS Blood and Transplant [NHSBT] (UK)

Sponsor details

Research & Development

National R&D Office

500 North Bristol Park

Northway

Bristol

England

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