

# Platelet Responsiveness and Outcome from Platelet Transfusion (PROmPT)

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

### Protocol serial number

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

## **Study type(s)**

Treatment

## **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(s)**

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

### **Key secondary outcome(s)**

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

### **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

## **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**

United Kingdom

England

### **Study participating centre**

**NHS Blood and Transplant (NHSBT)**

Cambridge

United Kingdom

CB2 2PT

## **Sponsor information**

### **Organisation**

NHS Blood and Transplant [NHSBT] (UK)

### **ROR**

<https://ror.org/0227qpa16>

## **Funder(s)**

### **Funder type**

Hospital/treatment centre

**Funder Name**

NHS Blood and Transplant [NHSBT] (UK)

**Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration