

# Platelet Process Improvement Project

<b>Submission date</b> 07/02/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 26/03/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/05/2014	<b>Condition category</b> Haematological Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

[http://www.ctu.mrc.ac.uk/research\\_areas/study\\_details.aspx?s=122](http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=122)

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CS06/2

## Study information

Scientific Title

Comparison of platelets stored for 2 - 5 versus 6 - 7 days in preventing and treating haemorrhage in thrombocytopenic patients: a randomised controlled trial

**Acronym**

PPIP

**Study objectives**

To test the null hypothesis that extension of the allowable storage period for platelet components to 7 days from the current standard of 5 days does not lead to any clinically significant reduction in their efficacy for preventing and treating bleeding in patients whose platelet count is low. Both platelets suspended in plasma and platelets suspended in an additive solution/plasma mixture will be studied.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Leeds (East) Research Ethics Committee on 18/05/2007 (ref: 07/Q1206/50)

**Study design**

Randomised, block, non-inferiority, matched pairs, cross-over design

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Not specified

**Study type(s)**

Other

**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**

Thrombocytopenia, haemorrhage

**Interventions**

Patients will be randomised to receive a sequence of transfusions in blocks of two, so that within each block there will be one allocation for standard 2 - 5 day old platelets, and one allocation for 6 - 7 day platelets, in random order. A maximum of 16 transfusions will be evaluated per patient before they are withdrawn from the trial. The duration of interventions depends upon the length of each in-patient stay as only transfusions received as an in-patient will provide the researchers with a post transfusion platelet count to enable calculation of a platelet increment.

Participants will be assessed for bleeding daily using a structured assessment form, either by medical or self-assessment. Routine blood tests will allow calculation of an 18 - 24 hour platelet increment following platelet transfusion.

## **Intervention Type**

Other

## **Phase**

Not Specified

## **Primary outcome measure**

The proportion of successful transfusions, of either 2 - 5 or 6 - 7 days, as measured by 18 - 24 hour Corrected Count Increment (CCI), within the first block. Platelet increment is defined as the post -transfusion platelet count minus pre-transfusion platelet count ( $\times 10^9/L$ ). The CCI is calculated from the platelet increment (PI), body surface area (BSA) in metres squared, and dose of platelets (PD) transfused ( $\times 10^{11}$ ).

$$CCI = PI \times BSA \times PD - 1$$

A successful transfusion is defined as a CCI greater than  $4.5 \times 10^9/L$ .

## **Secondary outcome measures**

1. Proportion of successful transfusions in all blocks
2. Mean 18 - 24 hour CCI following transfusions in the first block only
3. Mean 18 - 24 hour CCI following transfusions in all blocks
4. Proportion of days a patient has a bleeding score WHO grade 2 or more during the first and subsequent intervals between transfusions. Bleeding will be assessed and monitored daily using a structured assessment form. Assignment of bleeding grades to a modification of the WHO bleeding score will be performed by a computerised algorithm.
4. Interval (number of days) to the second and subsequent platelet transfusions
5. Incidence of acute reactions to each platelet transfusion

## **Overall study start date**

01/09/2007

## **Completion date**

31/12/2008

# **Eligibility**

## **Key inclusion criteria**

Adult (aged 16 or above) haemato-oncology patients who are thrombocytopenic because of bone marrow failure in Manchester Royal Infirmary and Bristol Royal Infirmary requiring platelet transfusion according to local and British Committee for Standards in Haematology (BCSH) guidelines.

## **Participant type(s)**

Patient

## **Age group**

Adult

**Sex**

Both

**Target number of participants**

100

**Key exclusion criteria**

1. Inherited or acquired clotting disorders
2. Inherited or acquired platelet function disorders
3. Acute promyelocytic leukaemia
4. Previously documented World Health Organization (WHO) grade 4 bleeding (debilitating blood loss)
5. Pregnant females
6. Splenomegaly
7. Immunological refractoriness to platelet transfusion

**Date of first enrolment**

01/09/2007

**Date of final enrolment**

31/12/2008

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Leeds Blood Centre**

Leeds

United Kingdom

LS15 7TW

## **Sponsor information**

**Organisation**

National Blood Service (UK)

**Sponsor details**

c/o Professor Marion Scott

National Blood Service

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**Sponsor type**

Government

**Website**

<http://www.blood.co.uk>

**ROR**

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

## Funder(s)

**Funder type**

Government

**Funder Name**

National Health Service 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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/08/2015		Yes	No