

Platelet Process Improvement Project

Submission date 07/02/2008	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 26/03/2008	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 20/05/2014	Condition category Haematological Disorders	☐ Individual participant data

Plain English summary of protocol

http://www.ctu.mrc.ac.uk/research_areas/study_details.aspx?s=122

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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)

Primary study design

Interventional

Study design

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

Study type(s)

Other

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 A maximum of 16 transfusions will be evaluated per patient before they are withdrawn from the trial.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(s)

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 $4.5 \times 10^9/L$.

Key secondary outcome(s)

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

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

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. 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

United Kingdom

England

Study participating centre

Leeds Blood Centre

Leeds

United Kingdom

LS15 7TW

Sponsor information

Organisation

National Blood Service (UK)

ROR

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

Funder(s)

Funder type

Government

Funder Name

National Health Service Blood and Transplant (NHSBT) (UK)

Results and Publications

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?
Results article	results	01/08/2015		Yes	No