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Platelet Process Improvement Project

Submission date
07/02/2008

Registration date
26/03/2008

Last Edited
20/05/2014

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Haematological Disorders

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Dr Sheila MacLennan

Contact details
Leeds Blood Centre
Bridle Path
Leeds
United Kingdom
LS15 7TW
+44 (0)7711 447412
sheila.maclennan@nbs.nhs.uk

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 A maximum of 16 transfusions will be evaluated per patient before they are withdrawn from the trial.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 (x 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 (x 10^11).

CCI = PI x BSA x PD-1

A successful transfusion is defined as a CCI greater than 4.5 x 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 platlet 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

Southmead Road
Bristol
United Kingdom
BS10 5ND
+44 (0)1179 912000
marion.scott@nbs.nhs.uk

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?
Results article	results	01/08/2015		Yes	No