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Risk factors for bleeding in haematology patients with low platelet counts

Submission date
15/06/2010

Recruitment status
No longer recruiting

Registration date
20/11/2012

Overall study status
Completed

Last Edited
12/11/2014

Condition category
Haematological Disorders

[_] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Platelets are a type of blood cell that help us to form clots and therefore stop bleeding. This study investigates why some haematology patients with very low platelet counts bleed and why other patients with the same number of platelets dont bleed.

Who can participate?
Patients aged 16 or over being cared for at Oxford University Hospitals NHS Trust or Bristol Royal Infirmary, who have been diagnosed with a haematological malignancy, who have received, are receiving or are going to receive chemotherapy or a stem cell transplant. These patients should have a low platelet count or are expected to have a low platelet count.

What does the study involve?
This study involves taking extra blood samples when the platelet count is low. These blood samples will look to see if there are any changes in the way the blood clots during treatment for haematological malignancies. A research nurse will also perform a daily bleeding assessment. This is because we would like to record any signs and symptoms of bleeding for up to 30 days, when the patient's platelet count is low. The study will stop once the patient's platelet count has recovered, or the patient has been discharged from hospital, or the patient has had 30 daily bleeding assessments.

What are the possible benefits and risks of participating?
The knowledge that we gain from this study will allow the development of further larger studies on the use of platelet transfusions. The outcome of these studies could improve the treatment of patients with haematological disorders in the future. This study does not alter the patient's treatment in any way. This study is therefore unlikely to benefit patients directly because their treatment will not be altered by any findings of this study. However, this study will hopefully lead to an improvement in the treatment of patients with a low platelet count in the future. Taking the extra blood samples is the only change from routine management. This is a very safe and low-risk procedure.

Where is the study run from?
John Radcliffe Hospital, Oxford, UK.

When is the study starting and how long is it expected to run for?
The study started in September 2010 and run until 2012.

Who is funding the study?
NHS Blood and Transplant and the British Society of Haematology (UK).

Who is the main contact?
Dr Lise Estcourt
lise.estcourt@nhsbt.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Dr Lise Estcourt

Contact details
Level 2
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9BQ
lise.estcourt@nhsbt.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Risk factors for haemorrhage in thrombocytopenic haematology patients: a pilot clinical investigation

Acronym
aTHenA

Study objectives

The primary objective is to identify those abnormalities of the haemostatic system that are clinically significant in patients presenting with an acute haematological malignancy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Berkshire Research Ethics Committee, 27/05/2010, ref: 10/H0505/47

Study design
Observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Causes of bleeding in patients with a haematological malignancy associated with severe thrombocytopenia.

Interventions
1. Blood sampling at enrolment into the study:
Once platelet count is < 50 x109/L blood samples will be taken three times a week until either platelet count recovery (defined as an unsupported platelet count ≥ 50 x109/L for 3 consecutive days), discharge from hospital or 30 days from the initiation of regular blood sampling.
2. Daily bleeding assessment (same as TOPPs study ISRCTN08758735):
Once platelet count is < 50 x 109/L bleeding assessments will be carried out daily until either platelet count recovery (defined as above), discharge from hospital or once 30 days of daily bleeding assessments have been completed.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To characterise abnormalities in the levels of
1. Thromboelastography (ROTEM/TEG)

2. Thrombin generation
3. Platelet function (PFA-100)
4. von Willebrand Factor (vWF)

Secondary outcome measures
1. The proportion of patients who have had a significant haemorrhage defined as a modified WHO grade 2, 3 or 4 haemorrhage. This was chosen as an outcome measure as it encompasses clinically relevant bleeding.
2. Platelet count
3. Haemoglobin (Hb)
4. Mean Platelet Volume (MPV)
5. Immature Platelet Fraction (IPF)

Overall study start date
01/09/2010

Completion date
01/09/2011

Eligibility

Key inclusion criteria
1. Adult patients with a haematological malignancy requiring myeloablative chemotherapy or a stem cell transplant
2. Aged 16 years or over
3. Confirmed diagnosis of a haematological malignancy
4. Received, are receiving or are going to receive myelosuppressive chemotherapy on this hospital admission with or without haematopoietic stem cell support (this includes patients undergoing haemopoietic stem cell transplantation -autograft or allograft)
5. Thrombocytopenic or expected to become thrombocytopenic with a platelet count of less than 50 x 10E9/L for at least 5 days
6. Will be treated as an in-patient during their period of thrombocytopenia
7. Able to comply with monitoring

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Inherited clotting disorder (e.g. haemophilia)
2. Patients need to remain on regular aspirin (or related drugs), or will require regular doses of anticoagulants (heparin), during the whole period of thrombocytopenia

3. Previously recruited to this study at any stage of their treatment
4. Diagnosed with or with a history of immune thrombocytopenia

Date of first enrolment
01/09/2010

Date of final enrolment
01/09/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Level 2
Oxford
United Kingdom
OX3 9BQ

Sponsor information

Organisation
NHS Blood & Transplant (NHSBT) (UK)

Sponsor details
c/o Professor Marion Scott
Southmead Road
Bristol
United Kingdom
BS10 5ND

Sponsor type
Government

Website
http://www.nhsbt.nhs.uk/

ROR
https://ror.org/0227qpa16

Funder(s)

Funder type
Not defined

Funder Name
NHS Blood & 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	01/08/2014		Yes	No
HRA research summary			28/06/2023	No	No