

# Risk factors for bleeding in haematology patients with low platelet counts

<b>Submission date</b> 15/06/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 20/11/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/11/2014	<b>Condition category</b> Haematological Disorders	<input type="checkbox"/> 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 don't 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  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Lise Estcourt

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## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Other

**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  $< 50 \times 10^9/L$  blood samples will be taken three times a week until either platelet count recovery (defined as an unsupported platelet count  $\geq 50 \times 10^9/L$  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  $< 50 \times 10^9/L$  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(s)**

To characterise abnormalities in the levels of

1. Thromboelastography (ROTEM/TEG)
2. Thrombin generation
3. Platelet function (PFA-100)
4. von Willebrand Factor (vWF)

**Key secondary outcome(s)**

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)

**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 haematopoietic stem cell transplantation -autograft or allograft)
5. Thrombocytopenic or expected to become thrombocytopenic with a platelet count of less than  $50 \times 10^9/L$  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

## Healthy volunteers allowed

No

## Age group

Adult

## Sex

All

## 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

United Kingdom

England

## Study participating centre

**Level 2**  
Oxford  
United Kingdom  
OX3 9BQ

## Sponsor information

**Organisation**  
NHS Blood & Transplant (NHSBT) (UK)

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

## Funder(s)

**Funder type**  
Not defined

**Funder Name**  
NHS Blood & 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?
<a href="#">Results article</a>	results	01/08/2014		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes