

# Randomised study to compare aspirin versus hydroxyurea/aspirin in 'intermediate risk' primary thrombocythaemia (PT) and hydroxyurea/aspirin versus anagrelide/aspirin in 'high risk' primary thrombocythaemia

<b>Submission date</b> 25/10/2000	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/10/2000	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 28/08/2012	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://www.cancerhelp.org.uk/trials/a-trial-looking-at-treatment-for-adults-with-primary-thrombocythaemia>

## Contact information

### Type(s)

Scientific

### Contact name

Prof AR Green

### Contact details

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## Additional identifiers

Clinical Trials Information System (CTIS)

2004-000245-38

**ClinicalTrials.gov (NCT)**

NCT00175838

**Protocol serial number**

AA3

## Study information

**Scientific Title**

**Acronym**

PT1

**Study objectives**

1. In 'low risk' patients: what is the incidence of vascular occlusion while receiving aspirin alone?
2. In 'intermediate risk' patients: does hydroxyurea reduce vascular occlusive events when added to aspirin?
3. In 'high risk' patients: does anagrelide reduce vascular occlusive events as effectively as hydroxyurea?
4. In 'high risk' patients: is anagrelide as effective as hydroxyurea in reducing elevated platelet counts?
5. What is the effect of the treatment modalities on quality of life?
6. Secondary objective In 'intermediate' and 'high risk' patients: does treatment modality alter the risk of leukaemic or myelofibrotic transformation?

Please note as of 08/02/2011 the anticipated end date of this trial has been extended from 31/10/2003 to 31/07/2012 and the participant number has increased from 1200 to 1600.

As of 28/08/2012 the anticipated end date of this trial has been extended from 31/07/2012 to 30/04/2014.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

South Thames Multi Centre Research Ethics Committee (now called the South East Research Ethics Committee) on 01/08/1997 (MREC ref: 97/1/004)

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Leukaemia

## **Interventions**

'Low risk': aspirin only

'Intermediate risk': aspirin/aspirin plus hydroxyurea

'High risk': aspirin plus hydroxyurea/aspirin plus anagrelide

## **Intervention Type**

Drug

## **Phase**

Phase III

## **Drug/device/biological/vaccine name(s)**

aspirin versus hydroxyurea/aspirin

## **Primary outcome(s)**

Vascular occlusion, haemorrhagic events, death, drug side-effects, transformation to acute leukaemia or myelofibrosis

## **Key secondary outcome(s)**

Not provided at time of registration

## **Completion date**

30/04/2014

## **Eligibility**

### **Key inclusion criteria**

All patients over 18 years of age meeting diagnostic criteria of PT

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

Not Specified

### **Key exclusion criteria**

Severe heart disease excludes patients from the 'high risk' study.

### **Date of first enrolment**

01/07/1997

**Date of final enrolment**

30/04/2014

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Department of Haematology**

Cambridge

United Kingdom

CB2 2QH

## Sponsor information

**Organisation**

Medical Research Council (MRC) (UK)

## Funder(s)

**Funder type**

Research council

**Funder Name**

Medical Research Council (MRC) (UK)

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

# 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 (high risk arm)	16/08/2012		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes