

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

Submission date 25/10/2000	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 25/10/2000	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 28/08/2012	Condition category Cancer	☐ 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

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Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00175838

Clinical Trials Information System (CTIS)

2004-000245-38

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)

Primary study design

Interventional

Study design

Randomised controlled trial

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?
Results article	results (high risk arm)	16/08/2012		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes