ISRCTN72251782 https://doi.org/10.1186/ISRCTN72251782

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 [X] 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

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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, 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