

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

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

Study website

<http://www.haem.cam.ac.uk/primary-thrombocythaemia/>

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

2004-000245-38

IRAS number**ClinicalTrials.gov number**

NCT00175838

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/07/1997

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

Age group

Adult

Lower age limit

18 Years

Sex

Not Specified

Target number of participants

1600

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**

England

United Kingdom

Study participating centre

Department of Haematology

Cambridge

United Kingdom

CB2 2QH

Sponsor information**Organisation**

Medical Research Council (MRC) (UK)

Sponsor details

20 Park Crescent

London

United Kingdom

W1B 1AL

+44 (0)20 7636 5422

clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

<http://www.mrc.ac.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

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 (high risk arm) | 16/08/2012 | | Yes | No |