

# Safety, compliance with and activity of Bezafibrate and medroxyProgesterone acetate (BaP) as non-toxic therapy against myeloid and lymphoid cancers

<b>Submission date</b> 16/09/2011	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 25/10/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 11/01/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://cancerhelp.cancerresearchuk.org/trials/trial-looking-new-combination-drugs-some-types-leukaemia-lymphoma>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

2011-001955-35

### Protocol serial number

RG\_11-054

# Study information

## Scientific Title

Single arm phase II trial assessing the safety, compliance with and activity of Bezafibrate and medroxyProgesterone acetate (BaP) as non-toxic therapy against myeloid and lymphoid cancers

## Acronym

BaP

## Study objectives

To test in patients with acute myeloblastic leukaemia (AML) or high risk myelodysplasia (RAEB2 WHO criteria), B cell Chronic Lymphocytic Leukaemia (CLL) and B cell Non Hodgkins Lymphoma (BNHL) the following outcomes of BaP administration over 18 weeks:

1. Safety
2. Compliance (feasibility of delivery)
3. Anti-cancer activity

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

NRES Committee East Midlands - Nottingham 2, 13/11/2012, ref: 11/EM/0426

## Study design

Phase II single arm four centre pilot study

## Primary study design

Interventional

## Study type(s)

Screening

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

Acute Myeloblastic Leukaemia or high risk myelodysplasia (RAEB2 WHO criteria) (AML), B cell Chronic Lymphocytic Leukaemia (CLL) and B cell Non Hodgkins Lymphoma (BNHL)

## Interventions

All patients will receive BaP. BaP is Bezafibrate at 6 x 400 mg twice daily and medroxyProgesterone acetate at 5 x 200 mg daily. Patients will commence BaP at registration and continue for 18 weeks where the primary endpoint will be assessed. Patient may continue beyond 18 weeks at the discretion of the treating clinician.

## Intervention Type

Drug

## Phase

Phase II

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

Bezafibrate, Medroxyprogesterone acetate

### **Primary outcome(s)**

1. Safety: The number of grade 3 and 4 Adverse Reactions and Serious Adverse Reactions (SARs) attributable to the trial drugs
2. Patient compliance: Percentage of allocated treatment taken
3. Activity:
  - 3.1. Haematological Response in the first 18 weeks of treatment
  - 3.2. Clinical Response in the first 18 weeks of treatment

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

Quality of life questionnaires:

1. EQ-5D
2. EORTC QLQ-C30

Measured at baseline, between week 7-11 and at the final assessment at week 18

### **Completion date**

10/09/2014

## **Eligibility**

### **Key inclusion criteria**

1. Patients with one of the following diagnoses:
  - 1.1. AML or high risk myelodysplasia (RAEB-2 WHO criteria)
  - 1.2. CLL
  - 1.3. BNHL
2. Be 18 years or older
3. Have given written informed consent

For AML and MDS

1. Haemopoiesis must be impaired by the disease as judged by an abnormal full blood count (FBC) (International Working Group response criteria in myelodysplasia) and, where there is doubt as to the cause of impaired haemopoiesis, there must be bone marrow aspirate evidence that impaired haemopoiesis is due to cancer involvement of the bone marrow.
2. Abnormal values are haemoglobin level less than 11 g/dL or red blood cells (RBC) transfusion dependence, platelet count less than  $100 \times 10^9/L$  or platelet-transfusion dependence, absolute neutrophil count less than  $1.0 \times 10^9/L$ . Pretreatment baseline measures of cytopenias are averages of at least two measurements (not influenced by transfusions, i.e. no RBC transfusions for at least 1 week and no platelet transfusions for at least 3 days) over at least 1 week prior to therapy.

For CLL and BNHL

1. Patients must have either measurable disease (tumour cells in blood at  $>5 \times 10^9/L$ , or lymphadenopathy  $> 1\text{cm}$ ) or bone marrow failure due to disease as stated above for MDS / AML.

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

Patient

### **Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Patient considered suitable for other forms of anti-cancer therapy (either accepted standard therapy or therapy in the context of a clinical trial) other than palliative corticosteroids or hydroxyurea
2. Estimated Glomerular Filtration Rate (eGFR) < 30ml/min
3. Patient known to be allergic to trial drugs
4. Patient has received treatment with any investigational medicinal product within the previous 28 days
5. Patient unable to swallow orally administered medications
6. Patient has uncontrolled seizures
7. Patient has active infection requiring systemic antibiotics, antifungal or antiviral drugs
8. Patient has concurrent severe and/or uncontrolled medical condition [e.g. severe chronic obstructive pulmonary disorder (COPD), severe Parkinsons disease] or psychiatric condition
9. Women of child-bearing potential and men who have partners of child-bearing potential who are not willing to practise effective contraception for the duration of the study and for three months after the last study drug administration
10. Pregnant or lactating women. Women of child bearing potential must have a negative urine or serum pregnancy test within 7 days prior to registration.

**Date of first enrolment**

01/10/2012

**Date of final enrolment**

01/07/2014

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Queen Elizabeth Hospital**

Stadium Rd

London

United Kingdom

SE18 4QH

**Study participating centre**  
**Heartlands Hospital**  
Bordesley Green E  
Birmingham  
United Kingdom  
B9 5SS

**Study participating centre**  
**Good Hope Hospital**  
Rectory Rd  
Sutton Coldfield  
United Kingdom  
B75 7RR

**Study participating centre**  
**Worcestershire Royal Hospital**  
Charles Hastings Way  
Worcester  
United Kingdom  
WR5 1DD

**Study participating centre**  
**New Cross Hospital**  
Wednesfield Rd  
WV10 0QP  
United Kingdom  
WV10 0QP

## **Sponsor information**

**Organisation**  
University of Birmingham (UK)

**ROR**  
<https://ror.org/03angcq70>

## **Funder(s)**

## Funder type

Charity

## Funder Name

Queen Elizabeth Hospital Charity (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	10/04/2019	10/12/2019	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Plain English results</a>			11/01/2024	No	Yes