

# Non-randomised trial of a lipid lowering drug and a steroid for the treatment of relapsed Burkitt's lymphoma in Blantyre, Malawi

<b>Submission date</b> 24/12/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 23/01/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/07/2014	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

A phase II non-randomised study of medroxyprogesterone acetate plus bezafibrate as adjunctive therapy in the treatment of relapsed Burkitt's lymphoma in Blantyre, Malawi

## Study objectives

That patients with relapsed Burkitt's lymphoma will respond to adjunctive therapy with bezafibrate and medroxyprogesterone acetate.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

University of Malawi College of Medicine Research and Ethics Committee, 01/11/2005, ref: COMREC P/05/06/467

## Study design

Interventional single centre non-randomised phase II study

## Primary study design

Interventional

## Secondary study design

Non randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Burkitt's lymphoma

## Interventions

The trial drugs are given orally, daily for 6 weeks:

1. Medroxyprogesterone acetate 4 mg/kg twice daily
2. Bezafibrate 200 mg daily or twice daily if weight greater than 20 kg

For participants 21 - 30 the trial drugs doses are increased to:

1. Medroxyprogesterone acetate 20 mg/kg once daily
2. Bezalip Mono one 400 mg tablet/10 kg body weight daily

For participants 31 - 40 the trial drugs doses are increased to:

1. Medroxyprogesterone acetate 20 mg/kg once daily
2. Bezalip Mono two 400 mg tablets/10 kg body weight daily

All patients will receive standard anti-Burkitt's lymphoma therapy with cyclophosphamide, vincristine and intrathecal methotrexate/hydrocortisone starting the first day of the second week.

### **Intervention Type**

Drug

### **Phase**

Phase II

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

Bezafibrate, medroxyprogesterone acetate

### **Primary outcome measure**

1. Response of Burkitt's lymphoma in the first week of trial therapy
2. Adverse events attributable to the trial drugs medroxyprogesterone acetate and bezafibrate

### **Secondary outcome measures**

1. Response to therapy
2. Disease-free survival
3. Overall survival

Follow-up to a minimum of a year.

### **Overall study start date**

01/02/2006

### **Completion date**

01/12/2009

## **Eligibility**

### **Key inclusion criteria**

1. Aged less than 14 years, either sex
2. Diagnosis of relapsed Burkitt's lymphoma confirmed by cytology/immunophenotyping
3. Negative pregnancy test if the patient is of childbearing potential
4. Informed consent, and the ability of the guardian and patient to co-operate with treatment and follow up must be ensured and documented

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

Patient

### **Age group**

Child

### **Upper age limit**

14 Years

**Sex**

Both

**Target number of participants**

40

**Key exclusion criteria**

1. Patient unable to swallow tablets
2. Patients living outside Malawi (follow up is not possible for patients living in Mozambique)
3. Pregnancy
4. Breast feeding

**Date of first enrolment**

01/02/2006

**Date of final enrolment**

01/12/2009

## **Locations**

**Countries of recruitment**

Malawi

**Study participating centre**

Department of Paediatrics,

Blantyre

Malawi

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## **Sponsor information**

**Organisation**

University of Malawi (Malawi)

**Sponsor details**

College of Medicine

Chichiri

Blantyre

Malawi

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**Sponsor type**

University/education

**Website**

<http://www.medcol.mw/>

**ROR**

<https://ror.org/04vtx5s55>

## Funder(s)

**Funder type**

University/education

**Funder Name**

University of Birmingham (UK) - Division of Immunity and Infection

## 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?
<a href="#">Results article</a>	results	01/03/2014		Yes	No