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

Submission date	Recruitment status	Prospectively registered
24/12/2008	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
23/01/2009	Completed	[X] Results
Last Edited	Condition category	Individual participant data
03/07/2014	Cancer	

## Plain English summary of protocol

Not provided at time of registration

## Contact information

#### Type(s)

Scientific

#### Contact name

Prof Elizabeth Molyneux

#### Contact details

Department of Paediatrics, College of Medicine University of Malawi Blantyre Malawi

## Additional identifiers

**Protocol serial number** 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

#### Study type(s)

Treatment

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

Burkitt's lymphoma

#### **Interventions**

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

- 1. Medroxprogesterone 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(s)

- 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

#### Key secondary outcome(s))

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

Follow-up to a minimum of a year.

#### 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

#### Healthy volunteers allowed

No

#### Age group

Child

#### Upper age limit

14 years

#### Sex

All

#### 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 3

## Sponsor information

#### Organisation

University of Malawi (Malawi)

#### **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**

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
Barrella callata	results	04/02/2044

Results article 01/03/2014 Yes No

Participant information sheet Participant information sheet 11/11/2025 No Yes