

# Rituximab adjunctive therapy for Burkitt's lymphoma

<b>Submission date</b> 25/05/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/06/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/11/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Burkitt's lymphoma is an uncommon form of non-Hodgkin lymphoma. It is a cancer that affects a type of white blood cells called lymphocytes. The aim of this study is to find out whether the addition of a single dose of the drug rituximab to standard anti-lymphoma treatment will improve outcomes in Burkitt's lymphoma, relapsed and resistant.

### Who can participate?

Children aged under 14 with Burkitt's lymphoma

### What does the study involve?

All patients receive the standard treatment for Burkitt's lymphoma and are randomly allocated into three groups. Group One receives one additional dose of 375mg/m<sup>2</sup> of rituximab on Day 15. Group Two receives one additional dose of 50mg/m<sup>2</sup> of rituximab on Day 15. Group Three receives no additional rituximab. The three groups are compared for the number of children in clinical complete remission at the end of chemotherapy and 1 year later.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

Queen Elizabeth Central Hospital (Malawi)

### When is the study starting and how long is it expected to run for?

June 2016 to March 2024

### Who is funding the study?

1. Alumni of University of Birmingham (UK)
2. The Scott Hampton Foundation for Burkitt's Research (UK)

### Who is the main contact?

Prof. Mark Drayson  
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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

National Health Sciences Research NHSRC #15/5ll28l

# Study information

## Scientific Title

An open-label, randomised, phase 2 study of rituximab as adjunctive therapy in the treatment of Burkitt's lymphoma at QECH, Blantyre, Malawi

## Acronym

RIBULY

## Study objectives

Addition of rituximab to standard anti-lymphoma therapy will improve outcome in newly diagnosed, relapsed and resistant Burkitt's Lymphoma.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

National Health Sciences Research Committee, Ministry Of Health, Lilongwe 3, Malawi, 12/06 /2015, ref: NHSRC #15/5ll28l

## Study design

Open-label randomised phase II study

## Primary study design

Interventional

## Study type(s)

Treatment

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

Burkitt's lymphoma

## Interventions

This study tests whether the addition of a single dose of rituximab to standard anti-lymphoma therapy will improve outcome in newly diagnosed, relapsed and resistant eBL. All patients will receive the standard therapy for Burkitt's lymphoma and will be randomised into 3 groups:

Group One will receive 1 additional dose of 375mg/m<sup>2</sup> of rituximab on Day 15

Group Two will receive 1 additional dose of 50mg/m<sup>2</sup> of rituximab on Day 15

Group Three will receive no additional rituximab

The study will compare between these three groups for the number of children in Clinical Complete Remission at the end of chemotherapy and a year later.

## Intervention Type

Drug

## Phase

Phase II

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

Not provided at time of registration

**Primary outcome(s)**

Clinical Complete Remission rate at end of chemotherapy

**Key secondary outcome(s)**

1. Clinical Complete Remission rate at one year post chemotherapy
2. Severe adverse effects of rituximab

**Completion date**

01/03/2024

**Eligibility****Key inclusion criteria**

1. Child <14 yrs of age with proven Burkitt's lymphoma (BL) or relapse or resistant BL
2. After full information, the guardians have given written informed consent, and the child if appropriate will be asked for assent
3. The guardian and patient will be willing and able to complete treatment and follow-up

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Child

**Upper age limit**

14 years

**Sex**

All

**Total final enrolment**

293

**Key exclusion criteria**

1. Patients known to be allergic to trial medications
2. Patients or their guardians who do not consent
3. Pregnant and/or breastfeeding patients

**Date of first enrolment**

20/06/2016

**Date of final enrolment**

01/03/2023

# Locations

## Countries of recruitment

Malawi

## Study participating centre

**Queen Elizabeth Central Hospital**

Paediatric Department

Blantyre

Malawi

PO Box 95

# Sponsor information

## Organisation

University of Malawi College of Medicine

## ROR

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

# Funder(s)

## Funder type

University/education

## Funder Name

Alumni of University of Birmingham, UK

## Funder Name

The Scott Hampton Foundation for Burkitt's Research

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from the TMG. Summary data including baseline characteristics and outcome data will be available after the primary publication for up to 5 years from the end of the study. Data will be shared with any researchers for whom the scope and purpose of the data sharing are

agreed by the TMG, all participants have agreed to use of data for research, no identifiable data will be released and patients will have a unique trial number assigned. The researchers encourage data sharing and all reasonable requests will be reviewed favourably.

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Abstract results</a>		20/10/2024	15/11/2024	No	No