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Rituximab adjunctive therapy for Burkitt's lymphoma

Submission date	Recruitment status	[X] Prospectively registered
25/05/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/06/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
15/11/2024	Cancer	

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/m2 of rituximab on Day 15. Group Two receives one additional dose of 50mg/m2 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

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/m2 of rituximab on Day 15
Group Two will receive 1 additional dose of 50mg/m2 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 measure
Clinical Complete Remission rate at end of chemotherapy

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

Overall study start date
20/06/2016

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

Age group
Child

Upper age limit
14 Years

Sex
Both

Target number of participants
A total of 180 cases are expected to be enrolled in 3 yrs

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

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Sponsor type
University/education

Website
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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

Publication and dissemination plan

Intention to publish date
30/06/2025

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?
Abstract results		20/10/2024	15/11/2024	No	No