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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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
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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?
Results article	results	01/03/2014		Yes	No