

Abstract 2522

## RANDOMISED CONTROLLED PHASE II TRIAL OF RITUXIMAB AS ADJUNCTIVE THERAPY IN THE TREATMENT OF BL FOR CHILDREN IN SUB-SAHARAN AFRICA.

Type: Late Breaking Abstract Submission

Topic: Late Breaking Abstract

Authors: George Chagaluka<sup>1</sup>, Francine Kouya<sup>2</sup>, Elizabeth Molyneux<sup>1</sup>, Glenn Mbah Afungchwi<sup>2</sup>, Janet Dunn<sup>3</sup>, Gulnaz Iqbal<sup>3</sup>, Simon Bailey<sup>3</sup>, Trijn Israels<sup>1</sup>, Chris Bunce<sup>3</sup>, [Farhat Khanim](#)<sup>3</sup>, Mark Drayson<sup>3</sup>; <sup>1</sup>Malawi, <sup>2</sup>Cameroon, <sup>3</sup>United Kingdom

### Background and Aims

Burkitt Lymphoma (BL) is one of the most common childhood cancers in sub-Saharan Africa with outcomes impacted by financial limitations and access to effective and affordable therapies. The aim of this trial was to see if the addition of rituximab improved responses when given as a single dose after the first cycle of chemotherapy.

### Methods

Randomised-controlled phase II trial of rituximab as adjunctive therapy for paediatric BL in Malawi and Cameroon. Patients were randomised between; no rituximab (NR) vs single low dose of 50mg/m<sup>2</sup> (LD) rituximab vs single standard dose of 375 mg/m<sup>2</sup> rituximab (SD) after the first chemotherapy cycle.

The trial was powered to detect 25% differences in patients achieving Complete Clinical Response (CCR) between treatment arms with 90% power and a 5% 2-sided significance level.

### Results

The trial recruited 293 children; 97 on NR, 98 on LD and 98 on SD. Median age was 8 years (IQR 6-11 years); 63% male; 30% mid-upper arm circumference (MUAC) of ≤13.5cm.

CCR at 12 months was assessed in 238 children. Overall, there were no significant differences between treatment arms in CCR: 49/72 (68%) SD, 47/84 patients (56%) LD and 48/82 patients (59%)(chi square p=0.28), or overall survival: NR vs LD (log rank p=0.98), NR vs SD (log rank p=0.09). However, in malnourished children (MUAC ≤13.5cm), a significantly higher CCR rate was achieved with SD vs NR (16/24 67% SD vs 7/21 33% NR, p=0.03) (10/42 45% LD vs 7/21 33% no rituximab, p=0.42). Overall survival was also significantly improved (SD compared to NR, p=0.005). 70 deaths were reported from 238 patients; 27 (33%) on NR, (28 (33%) on LD and 15 (21%) on SD.

### Conclusions

Whilst there was no difference in CCR or survival between trial arms overall, the addition of SD to chemotherapy significantly improved CCR and survival in malnourished children with eBL.

Print