Clinical trials design and methodology

PO - (8448) - ADVERSE DRUG REACTION TO TWO ARTEMISININ BASED COMBINATION THERAPIES- ARTEMETHER-LUMEFANTRINE AND ARTEMISININ-PIPERAQUINE IN CHILDREN WITH ACUTE UNCOMPLICATED MALARIA IN IBADAN, NIGERIA

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ABSTRACT

BACKGROUND: Malaria remains a public health problem in Sub-Saharan Africa especially amongst children and pregnant women. Artemisinin-based combination therapy (ACT) is now the treatment of choice. Adverse drug reactions (ADR) have been observed to ACTs.

This study aims to determine the incidence, pattern of presentation and factors associated with ADRs to artemether-lumefantrine(AL) and artemisinin-piperaquine(AP) among children with acute uncomplicated malaria in Ibadan, Nigeria.

METHODS: Children aged 2-10 years with acute uncomplicated malaria who met the inclusion criteria were enrolled, randomized to receive one of the study drugs (AL or AP) and followed up for 28 days. Monitoring for ADR was based on history from the parent/guardian and/or child for occurrences of treatment emergent signs and symptoms as well as from abnormalities of laboratory investigations -Full blood count and blood chemistry. Causality assessment for the ADR was by the Naranjo algorithm scale while the severity was assessed using the Hartwig’s severity scale.

RESULTS: 114 children were enrolled; six defaulted and were not available for follow up. There were 61 (56.5%) males. The mean age of enrollees was 65.1 ± 30.0 months. Fever was the most prevalent presenting complaints occurring in 108 (100%) enrollees. Observed ADRs were cough, diarrhea, loss of appetite, abdominal pain, rash, fever, irritability, insomnia and headache but the differences were not statistically significant between the two groups. The incidence of ADR to both ACTs was 12/1000 patients per day. Prevalence of ADR to AL was 14% and AP was 11%, this was not statistically significant. All ADRs were mild. No notable associated factor to ADR was detected in this study.

CONCLUSION: Both AL and AP were found to be safe in the study population.