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In vivo efficacy of artemether-lumefantrine and artesunate-amodiaquine for the treatment of uncomplicated falciparum malaria in children: A multisite, open-label, two-cohort, clinical trial in Mozambique

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Introduction: The World Health Organization (WHO) currently recommends the use of artemisinin-based combinations (ACTs) for the treatment of uncomplicated P. *falciparum* malaria. With the first evidence of emergence of artemisinin resistance in South East Asia, it has now become critical to conduct robust surveillance of *in vivo* efficacy of ACTs in malaria-endemic areas where they have been deployed as first line treatment.

Method: We conducted two consecutive clinical surveillance studies of the efficacy and safety of two ACTs (artemether-lumefantrine, AL and amodiaquine-artesunate AQ-AS, first and second line policy respectively) in five sentinel health posts across Mozambique. Directly observed administration of the study drugs to children aged 6 months- <5 years was conducted, followed by 3 days consecutive, and weekly visits for 28 days, following the WHO 2009 protocol.

Results: Four-hundred and thirty-nine (AL cohort; five sites) and 261 (ASAQ cohort, three sites) children were recruited to the study. Day 28 PCR-corrected efficacy for AL was 96.0% (335/339; 95% CI: 93.4-97.8), while for ASAQ it was 99.6% (232/233; 95% CI: 97.6-99.9). The majority of recurring parasitaemia cases throughout follow-up was shown to be re-infections by PCR. Both drugs were well tolerated, with the most frequent adverse event being vomiting (AL 4.5% [20/439]; ASAQ 9.6% [25/261]) and no significant events deemed related to the study drugs.

Conclusion: This study confirms that both AL and ASAQ remain highly efficacious and well tolerated for the treatment of uncomplicated malaria in Mozambican children. Studies such as these should be replicated regularly in the selected surveillance sentinel sites to continuously monitor the efficacy of these drugs and to rapidly detect any potential signs of declining efficacy to ACT, the mainstay of malaria treatment.

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