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Open label trial on efficacy of Artemether/Lumefantrine (Coartem®) against uncomplicated *Plasmodium falciparum* malaria in Metehara, Eastern Ethiopia

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Aim: Based on WHO recommendation, this study was conducted to handle early changing malaria trends and the threat of emerging artemisinin resistance by Plasmodium parasite

Methods: This is a 28 day an open-label in vivo trial conducted from Oct to Jan 2014/15. As per the criteria set by WHO, febrile and malaria-suspected outpatients in health centers were employed to study. A standard six-dose regimen of AL was administered over three days and followed up for measuring therapeutic responses over 28 days.

Results: Of the 91 study subjects, 83 responded adequately at day 28. The rest 6 were censored by withdrawal and two cases were found late treatment failures. No early treatment failure was observed. As per protocol, the overall PCR-uncorrected and corrected cure rates were 97.6% (95% CI: 93.6-99.5) and 98.8% (CI: 93.5-100%), respectively. No asexual or sexual parasite was detected on day 3 and onwards. Fever clearance rate was above 95% on day 3; limited percentage delayed that might have been attributed to the metabolic products of malaria parasites. Hemoglobin recovery was significant (P<0.001) from 12.39 g/dl at day 0 to 13.45 g/dl on day 28. No serious drug reaction was observed except some reports of repeated cough and oral ulceration in children.

Conclusion: This study showed high efficacy and good tolerability of Coartem®, which suggests the safe continuation of the drug as first-line treatment for uncomplicated P. falciparum malaria in study area. This study recommends further studies to include the measurement of plasma drug level to evaluate the effect in relation to parasite and fever clearance rates.

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