

Efficacy and safety of the six-dose regimen of artemether-lumefantrine in pediatrics with uncomplicated plasmodium falciparum malaria: a pooled analysis of individual patient data

Michael Makanga, Zul Premji, Catherine Falade, Juntra Karbwang, Edgar A. Mueller, Kim Andriano, Philip Hunt, and Patricia Ibarra de Palacios

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Patient data from eight clinical trials were pooled and analyzed to study the efficacy and safety of the six-dose versus four-dose regimen of artemether-lumefantrine (coartemether; Coartem) in children weighing 5–25 kg. A total of 544 patients with uncomplicated *P. falciparum* malaria (six-dose: 343; four-dose: 201), matched for demographic and baseline characteristics and individual coartemether doses were included in the analysis. Analysis of day 28 cure rate based on the intention-to-treat and evaluable populations yielded corrected cure rates for the six-dose regimen of 93% and 96% compared with 61% and 76%, respectively, for the four-dose regimen ($P < 0.0001$ for both comparisons). Similarly high cure rates were achieved with the six-dose regimen in non-immune infants weighing as little as 5 kg. The six- and four-dose regimens were equally well tolerated. The main finding of this analysis is that the six-dose regimen of coartemether is safe and more efficacious than the four-dose regimen in children.