

Publication

Artesunate-mefloquine combination therapy in acute Plasmodium falciparum malaria in young children: a field study regarding neurological and neuropsychiatric safety

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ABSTRACT: BACKGROUND: Mefloquine-artesunate combination therapy for uncomplicated falciparum malaria is one of the treatments used in African children. Data concerning neurological safety in adults and children treated with mefloquine and artesunate combination therapy is well documented in Asia. Safety data for neurological and neuropsychiatric side effects of mefloquine and artesunate combination therapy in African children are scarce, although WHO recommends this therapy in Africa. METHODS: A phase IV, open label, single arm study was conducted among African children between 10 and 20 kg with acute uncomplicated falciparum malaria. They were treated over three consecutive days with a paediatric fixed-dose combination of artesunate (50 mg/d) and mefloquine (125 mg/d). Parasitological, clinical and neurological examinations and standardized questions about neuropsychiatric symptoms were carried out on days 0, 4, 7, 28 and 63. The primary objective was to assess the neurological and neuropsychiatric safety of artesunate-mefloquine combination therapy in young children. RESULTS: From December 2007 to March 2009, 220 children with uncomplicated Plasmodium falciparum malaria were treated with artesunate and mefloquine. 213 children were analysed according to study protocol. 50 neurological and neuropsychiatric adverse events occurred in 28 patients. Eleven drug-related neurological and neuropsychiatric adverse events occurred in eight patients. Sleeping disorders were present in 2.3%, neurological disorders in 1.4%, neuropsychiatric disorders in 1% and eating disorders in 0.5% of the patients. Adverse events were of mild to moderate intensity and resolved spontaneously. CONCLUSION: African children showed a low percentage of self-limited neurological and neuropsychiatric adverse events, confirming studies on neurological safety in Asian children treated with artesunate and mefloquine. Sleeping disorders were most frequently observed

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