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Original article

The comparative efficacy and tolerability of CGP 56697 (artemether+lumefantrine) versus halofantrine in the treatment of uncomplicated falciparum malaria in travellers returning from the Tropics to The Netherlands and France

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Abstract

CGP 56697 (Riamet[®], C) is a new oral anti-malarial drug composed of artemether and lumefantrine (benflumetol) which combines the fast, short-acting artemether for rapid parasite clearance with the prolonged action of lumefantrine for intended radical cure. In this double-blind, comparative trial, the efficacy and tolerability of CGP 56697, given as a course of 4 A —4 tablets over 48 h, was compared to halofantrine, given as 3 A —2 tablets over 12 h with a second course 1 week later. Patients (mostly non-immune) with

acute, uncomplicated *Plasmodium falciparum* infection were randomly assigned to either CGP 56697 ($n=51$) or halofantrine ($n=52$). CGP 56697 proved superior with respect to parasite clearance time (median 32 vs. 48 h, $P<0.001$) and parasite reduction at 24 h (median 99.7 vs. 89.6%, $P<0.001$) with a non-significant difference in resolution of fever (median 24 vs. 32 h, $P=0.835$). However, a 28-day cure rate of 82% was observed for CGP 56697 and 100% for halofantrine. Significant QTc prolongations (>30 ms) were seen 6–12 h after halofantrine intake but not after CGP 56697 intake. CGP 56697 is an effective, well-tolerated treatment for uncomplicated falciparum malaria but for this dosing regimen the recrudescence rate is unacceptably high (18%). For travellers contracting malaria abroad, we propose a six-dose regimen of CGP 56697 over 3 days.



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Keywords

Artemether; Benflumetol; CGP 56697; Efficacy; Halofantrine; Lumefantrine; Malaria; QTc; Randomised controlled double-blind trial; Riamet; Tolerability; Traveller; Treatment

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amendment, and according to the principles of good clinical practice, as defined by the EC guidelines and Recommendations III/3976/88-EN. The study was approved by the appropriate local Ethics Committees and written informed consent was obtained from all patients.

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