

Tropical Doctor

Existence of antimalarial formulations with low bioavailability in Tanzania

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Abstract

The main objective of this work was to assess the relative bioavailability of two tablet formulations containing sulfadoxine/pyrimethamine (SP) and marketed in Tanzania. Twelve healthy volunteers were randomized to receive a single oral dose of three SP tablets each containing 500 mg sulfadoxine (SDX) and 25 mg pyrimethamine (PYR) in a form of either A (a locally manufactured SP tablet formulation, manufactured by a local pharmaceutical industry in Tanzania) or B (Fansidar[®], Hoffmann La Roche, Basel, Switzerland, an innovator's SP) after an overnight fasting. Serial blood samples (100 μ L) were collected from a finger prick in duplicate up to 10 days and dried on Whatman[®] filter paper. The samples were assayed for SDX and PYR using high-performance liquid chromatographic methods. Pharmacokinetic parameters of SDX and PYR were estimated by single compartment method. The pharmacokinetics of formulation A - maximum plasma concentration, the areas under the plasma concentration - time curve and the relative bioavailability (A versus B) were significantly lower than those of formulation B ($P < 0.1$). These observed differences indicate bioinequivalence between the two products.