Pharmacy and Poisons Board
Online clinical trials
Submitted Application : (ECCT/17/08/09)

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Abstract of Study:

Resistance to artemisinins and their partner drugs resulting in high treatment failure with artemisinin-based combination therapies (ACTs) severely threatens treatment of falciparum malaria. A spread of artemisinin and partner drug resistance to Sub-Saharan-Africa would have devastating consequences. Currently, there is no good alternative to ACTs for the treatment of uncomplicated falciparum malaria. This study aims to evaluate two alternative treatments with existing antimalarials for the treatment of uncomplicated Plasmodium falciparum infections in children in Kenya. The synthetic trioxolane arterolane maleate (OZ277), marketed in combination with piperaquine (PPQ) under the brand name Synriam®, is a promising new antimalarial drug combination to treat artemisinin resistant falciparum malaria. It is produced in India by the company Ranbaxy and is likely to be affordable in Lower Middle Income Countries. The use of multiple drugs with independent mechanisms of action aims to reduce emergence of drug resistance and is common practice in a range of human diseases, including HIV and tuberculosis. The triple combination dihydroartemisinin-piperaquine (available in Sub-Saharan Africa as Artekin) with mefloquine (now off-patent) has been shown to be as tolerable and safe as the more usual double combination dihydroartemisinin- piperaquine). The combination arterolane-piperaquine with mefloquine (where the DHA is replaced by arterolane) might be a very valuable addition to the potential future arsenal of combination drugs. TACT (i.e. triple artemisinin combination therapy), rather than double therapies with ACTs, might become the new standard treatment to prevent spread of resistance. We propose a randomised controlled clinical trial comparing the safety, tolerability, therapeutic efficacy and pharmacokinetics and pharmacodynamics of arterolane-piperaquine, arterolane-piperaquine plus mefloquine versus artemether-lumefantrine.in children with uncomplicated falciparum malaria in Kilifi, Kenya. This study will also provide an up to date insight on the current presence of antimalarial resistance in this site. In addition, all children will be treated with a single low dose of primaquine according to WHO guidelines, in order to prevent onward transmission of parasites to mosquitoes. We will recruit 219 patients aged 2 years to 12 years with acute uncomplicated falciparum malaria in Kilifi County Hospital. The primary endpoint will be day 42, PCR corrected assessments of adequate clinical and parasitological response (ACPR). In addition, we will collect data on parasite clearance during treatment, on adverse events, and on drug levels.

Study Title:

An open-label randomised trial to assess the therapeutic efficacy and tolerability of arterolane-piperaquine plus single low dose primaquine versus arterolane-piperaquine plus mefloquine and single low dose primaquine versus artemether-lumefantrine plus single low dose primaquine in the treatment of uncomplicated falciparum malaria in children in Kenya.