Clinical trials design and methodology

**OC - (8459) - ASSESSMENT OF PARASITE CLEARANCE AFTER REPEATED TREATMENT WITH ARTESUNATE AMODIQUINE, DIHYDROARTEMINININE-PIPERAQUINE, PYRONARIDINE-ARTESUNATE IN MALARIA PATIENTS IN BURKINA FASO**

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**Background.**

Reports from southeast Asia showed delayed of parasite clearance after treatment with known artemisinine based combination therapies, the first line treatment for malaria. We then carried out a study in the framework of WANECAM clinical trial to assess comparatively the parasite clearance time and rate from *P. falciparum* malaria patients repeatedly treated with the Artesunate-Amodiquine (ASAQ), Dihydroartemisinin-Piperaquine (DHA-PQ) and Artesunate-Pyronaridine (PYR).

**Methods.**

A randomized, phase III/IV comparative, multicentre, open-label parallel 3 arms trial was conducted in Banfora Health District area comparing the efficacy of a three-day regimen of DHA-PQ, PYR with ASAQ for the treatment of children (above 6 months) and adults with uncomplicated falciparum malaria. From August 2012 to December 2013 each randomized patient was followed up for 42 day over a period of two years. Treatment was directly observed, and blood smear samples were collected twice daily (12 h ± 2 h) until parasite clearance.

The endpoints of the present sub-study were parasite clearance rate and time. The secondary endpoints included PCR-corrected and uncorrected cure rates.

**Results**

Out of 2843 screened patients, 763 were recruited for parasite clearance endpoint analyses. The median parasite clearance time (PCT) was 24.1 h (2-sided 95% CI, 24.0 to 24.2h), 23.9h (2-sided 95% CI, 23.8 to 24.0h) and 24.2 h (2-sided 95% CI, 24.1 to 24.5h), in Pyronaridine - Artesunate, Artesunate-Amodiaquine and Dihyroartemisinine-Piperaquine, respectively. The PCR-corrected efficacy rates were estimated at 99.8%; 99.7%;99.9%, at day 28 and 99.3% ; 99.7% 99.9% in Pyronaridine-Artésunate, Artesunate-Amodiaquine and Dihyroartemisinine-Piperaquine, respectively.

**Conlusions**
The parasite clearance times were comparable among the three ACTs arms of treatment and their efficacy was comparable and higher than 99%. There is no delay in parasite clearance time (PCT ≥ 72 h).