Clinical trials design and methodology

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

Soulama, Issiaka (Burkina Faso)¹; Sirima, Sodiomon B (Burkina Faso)³
1 - Centre National de Recherche et de Formation sur le Paludisme

Background.

Reports from southeast Asia showed delayed of parasite clearance after treatment with known artemisinin 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-Artesunate, Artesunate-Amodiaquine and Dihyroartemisinine-Piperaquine, respectively.

Conclusions
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).