Artemether-lumefantrine Vs co-formulated Amodiaquine + Artesunate for the treatment of uncomplicated falciparum malaria: a randomized open-label trial to evaluate the effectiveness of the Burkina Faso new drug policy

Halidou TINTO[1,2]; Jean Eric Ouédraogo[3], Issaka Zongo[1]; Noèl Rouamba[1]; Innocent Valéa[1],
Jean Bosco Ouédraogo[1,2], Tinga Robert Guiguemdé [2], Umberto d'Alessandro[4]

[1] Institut de Recherche en Science de la Santé (IRSS-DRO)
[2] Centre Muraz
[3] Burkina Faso National Malaria Control Program
[4] Institute of Tropical Medicine

Financial and technical support:
Malaria Consortium, UK / **W**est **A**frica **N**etwork **II** for **M**onitoring **A**nti-malarial **T**reatment
(WANMAT II), Burkina Faso;
Institute of Tropical Medicine (ITM), Antwerp, Belgium.

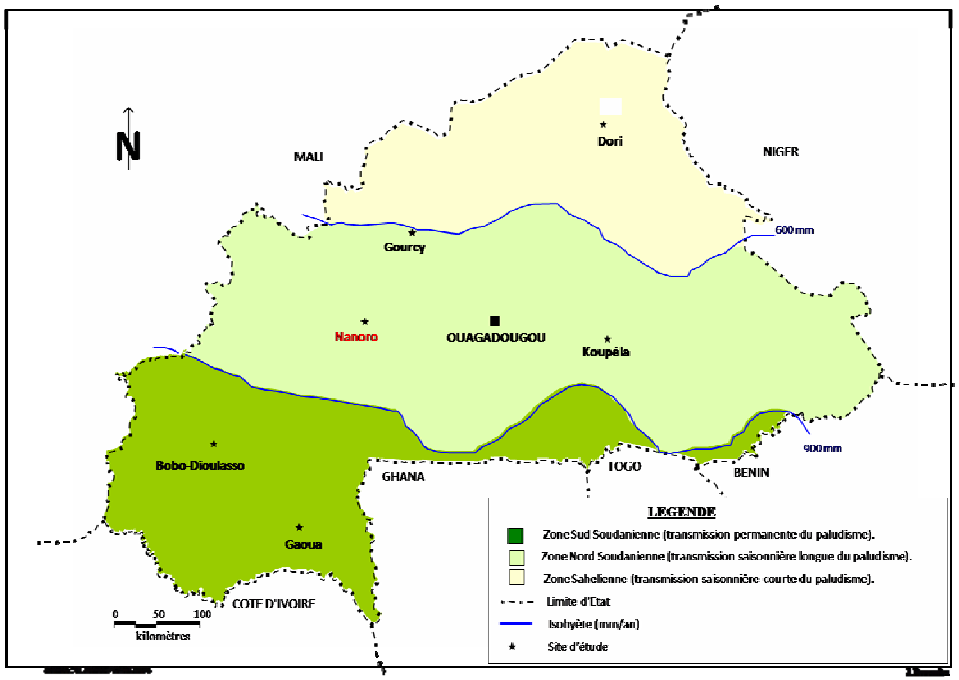
Objectives

- **Primary objective**
  - To establish the effectiveness of AQ+AS and AL, when given to children with uncomplicated malaria

- **Secondary objectives**
  - To determine the safety of the 2 ACTs in children with uncomplicated malaria treated as outpatients.
  - To determine the impact of the two ACTs on the incidence of clinical malaria in children treated as outpatients.

Methods (1)

- **Study site:** Nanoro, Burkina Faso (about 131,710 inhabitants)
- **Malaria:** Holo-endemic, with transmission peak in the rainy season



- **Study population:** Children 6-59 months of age.
- **Treatment:** patients will be randomly assigned to treatment with AL or AQ+AS.
- **Laboratory procedures:**
  - *P. falciparum infection analysis (Blood smears),*
  - *Hematology (Hemoglobin)*
  - *Genotyping (msp1 & msp2)*
- **Sample size:** 170 children per arm
- **Follow-up :** 42 days
- **Duration:** One year (08/2007-08/2008)

Methods (2)

- **Outcome measures**
  - ***Primary end points***:
    - Effectiveness: Treatment failure (TF) up to day 28 (PCR adjusted and unadjusted)
    - Safety: patients will be followed up to 42 days for possible development of adverse events.
  - ***Secondary endpoints***
    - Treatment failure up to day 42 (PCR adjusted and unadjusted)
    - Parasite and fever clearance;
    - Gametocytes (prevalence and density) at day 7, 14, 21, 28, 35 and 42;
    - Hb changes at day 28
- **Statistical analysis**
  - The primary objective for this study is to assess the difference between the 2 treatment groups based on parasitological cure rate, PCR corrected, at Day 28.
  - The difference between the treatment groups along with a 95% confidence interval around this difference will be presented.

Results

- Protocol approved by the centre Muraz EC.

- Site preparation in progress:
  - Study team is recruited.
  - Training of the study team (Protocol, Study procedures, GCP / GLP) planned for 1st week of august.
  - Procurement of study material is ongoing.

- 1st patient recruitment expected for mid-august 2007

Discussion & Conclusions

- Burkina Faso has adopted the new drug policy in February 2005. However this is not yet implemented.
- This study will be conducted in collaboration with the National Malaria Control Program.
- Such close relationship is a guarantee for the rapid uptake of the study's results for the review and modification of the new national antimalarial drug policy if needed.
- Therefore, at the end of the study, a report containing all results and comments will be send to the Ministry of Health through the NMCP.

Future perspectives

- Setting-up of a pharmacovigilance system for ACTs in the study area.

- Investigations on the relationship between the antimalarial drug resistance molecular markers and ACTs treatment failures.