

Thailand and the Thai-Burma border

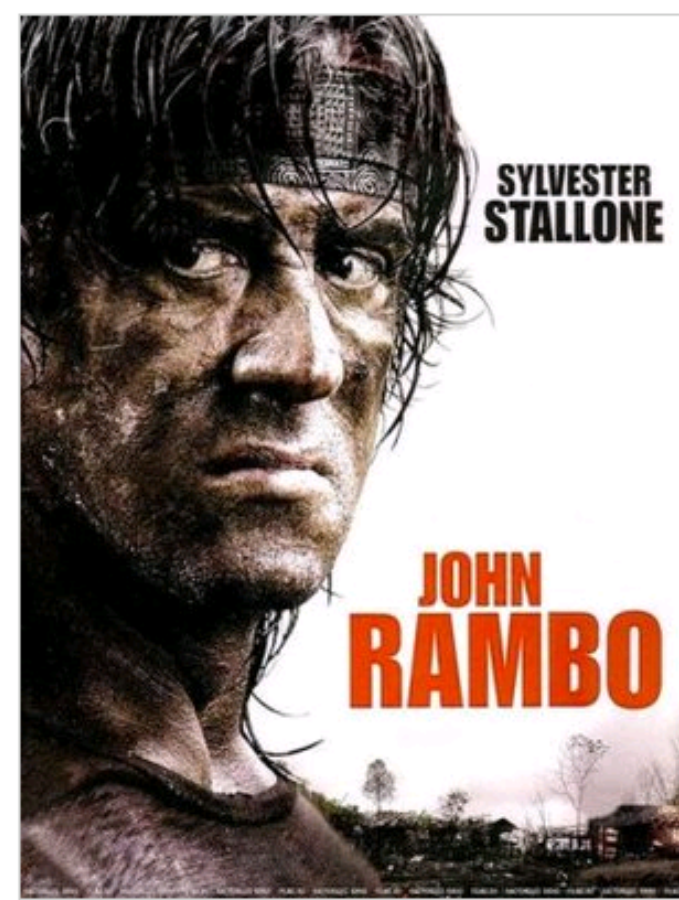
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TO SET THE SCENE



migrant
clinics and
hospital in a
refugee camp



Hospital in Mae La Refugee Camp





**4 migrant clinics along
the border – malaria,
pregnant women,
children, other
infections**



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Trial record **1 of 1** for: malaria DMA

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Randomised Trial of 3 Artemisinin Combination Therapy for Malaria in Pregnancy (DMA)

This study has been completed.

Sponsor:
University of Oxford

Information provided by (Responsible Party):
University of Oxford

ClinicalTrials.gov Identifier:
NCT01054248

First received: January 21, 2010
Last updated: September 13, 2016
Last verified: September 2016
[History of Changes](#)

PI = Rose McGready
My role: protocol, ethics
submission, trial monitoring, GCP
training, and consulting the CAB

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► Purpose

This is a randomised, open label trial, comparing standard dose of dihydroartemisinin-piperaquine (DP) with standard fixed artesunate-mefloquine regimen (MAS3) and with a longer regimen of artemether-lumefantrine (ALN+) in the treatment of uncomplicated malaria in pregnant women. The sample size is 335 women in each arm which would be 1005 women in total. Pregnant patients in 2nd and 3rd trimester with acute uncomplicated malaria who meet eligibility criteria will be asked to participate in the study. The primary objective is to determine if the efficacy of DP and MAS3 are superior to ALN+ in the treatment of uncomplicated malaria in pregnancy. The study will also incorporate a dense pharmacokinetic

Tak Province Border Community Ethics Advisory Board



Ethical & practical challenges: General

The Thai-Burma border

- Karen & Burmese migrant/refugees
 - Good antenatal care not available in Burma
 - Legal status?

In general

- Minimum age 18 years old (EC conservative)
- Emancipated minor (status unclear)
- No specific guidelines in Thailand (adapt from GCP, CFR)

Soe Soe

Soe Soe works on a corn plantation in an area of endemic malaria in Myanmar. She is four months pregnant.

One day, SS woke up with a fever. She walked for two hours, then cross the border to Thailand.

The doctors told her that she had malaria and asked her if she wanted to participate in a randomized controlled trial. SS understood what the study was about and wanted to participate in the study. But...she is 15 years old

SS cannot participate in the trial.

Ethical & practical challenges: the DMA Study

- Alternative to participation – same drugs
- What's different from routine care – randomisation, extra blood test, extra visits, regular follow up
- It's a pragmatic trial – but many regulatory hurdles
- Sample size difficult to achieve
- What about pregnant women under 18?

If Soe Soe were a Thai citizen...

(Thailand has the most teenage pregnancies in SEA)

- She must obtain a consent from one of her parent or;
- She can register her marriage at a district administrative office with consent from one parent - emancipation
- Or file an application to the Court to give consent for marriage

Here's another issue

Compulsory pregnancy tests for all women of childbearing age, sometimes every visit