

# Efficacy and safety of artesunate and sulfadoxine-pyrimethamine and artemether-lumefantrine for the treatment of uncomplicated Plasmodium falciparum malaria in low to moderate sentinel sites in Sudan

|                                        |                                                          |                                                      |
|----------------------------------------|----------------------------------------------------------|------------------------------------------------------|
| <b>Submission date</b><br>14/08/2007   | <b>Recruitment status</b><br>No longer recruiting        | <input type="checkbox"/> Prospectively registered    |
|                                        |                                                          | <input type="checkbox"/> Protocol                    |
| <b>Registration date</b><br>15/08/2007 | <b>Overall study status</b><br>Completed                 | <input type="checkbox"/> Statistical analysis plan   |
|                                        |                                                          | <input type="checkbox"/> Results                     |
| <b>Last Edited</b><br>11/09/2007       | <b>Condition category</b><br>Infections and Infestations | <input type="checkbox"/> Individual participant data |
|                                        |                                                          | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

### Protocol serial number

RPC220

# Study information

## Scientific Title

## Study objectives

To assess the efficacy of the first (artesunate and sulfadoxine-pyrimethamine) and second line treatment (artemether-lumefantrine) for the treatment of uncomplicated Plasmodium falciparum infections in different sentinel sites in Sudan.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from:

1. Federal Ministry of Health (Sudan) on the 3rd May 2007
2. Ethical Research Committee of the World Health Organization (WHO) on the 11th June 2007 (ref: RPC220)

## Primary study design

Interventional

## Study design

One-arm surveillance study

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Malaria

## Interventions

Each patient will receive both:

1. Artemether-lumefantrine six consecutive doses according to manufacturer recommendation over three days orally (per os)
2. Artesunate 12 mg/kg over three days per os and sulfadoxine-pyrimethamine 1/2 tablet 500 mg - 25 mg/10 kg single dose per os

Principal Investigator:

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## Intervention Type

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Artesunate, sulfadoxine-pyrimethamine, artemether-lumefantrine

**Primary outcome(s)**

Adequate clinical and parasitological response Polymerase Chain Reaction (PCR) corrected.

**Key secondary outcome(s)**

Incidence of adverse events.

**Completion date**

30/11/2007

## **Eligibility**

**Key inclusion criteria**

1. Aged over 6 months old
2. Infection with *P. falciparum*
3. Parasitaemia, 1000 - 100 000 asexual forms per  $\mu$ l
4. Axillary temperature of 37.5°C or oral/rectal temperature of 38°C
5. Ability to swallow oral medication
6. Ability and willingness to comply with the study protocol for the duration of the study and to comply with the study visit schedule
7. Informed consent from the patient or from a parent or guardian in case of children

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Not Specified

**Sex**

**Key exclusion criteria**

1. Presence of general danger signs among children less than 5 years old or other signs of severe and complicated *falciparum* malaria according to current WHO definitions
2. Mixed or mono-infection with another *Plasmodium* species
3. Presence of severe malnutrition (defined as a child whose weight-for-height is below -3 standard deviation or who has symmetrical oedema involving at least the feet)
4. Presence of febrile conditions due to diseases other than malaria (measles, acute lower tract respiratory infection, severe diarrhoea with dehydration, etc.), or other known underlying chronic or severe diseases
5. History of hypersensitivity reactions to any of the drug(s) being tested or used as alternative

treatment  
6. Pregnancy or lactation

**Date of first enrolment**  
01/08/2007

**Date of final enrolment**  
30/11/2007

## **Locations**

**Countries of recruitment**  
Sudan

Switzerland

**Study participating centre**  
**World Health Organization**  
Geneva-27  
Switzerland  
CH-1211

## **Sponsor information**

**Organisation**  
World Health Organization (WHO)/HIV/AIDS, Tuberculosis and Malaria (HTM) - Global Malaria Programme

**ROR**  
<https://ror.org/01f80g185>

## **Funder(s)**

**Funder type**  
Research organisation

**Funder Name**  
World Health Organization (WHO) (Sudan)

**Alternative Name(s)**  
, , Всемирная организация здравоохранения, Organisation mondiale de la Santé,  
Organización Mundial de la Salud, WHO, , ВОЗ, OMS

**Funding Body Type**

Government organisation

**Funding Body Subtype**

International organizations

**Location**

Switzerland

**Results and Publications**

Individual participant data (IPD) sharing plan

IPD sharing plan summary