# 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

Submission date	Recruitment status	Prospectively registered
14/08/2007	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
15/08/2007	Completed	☐ Results
Last Edited	Condition category	☐ Individual participant data
11/09/2007	Infections and Infestations	Record updated in last year

# Plain English summary of protocol

Not provided at time of registration

## Contact information

# Type(s)

Scientific

#### Contact name

Dr Pascal Ringwald

#### Contact details

World Health Organization 20 Avenue Appia Geneva-27 Switzerland CH-1211 +41 (0)22 791 34 69 ringwaldp@who.int

# 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)

#### Study design

One-arm surveillance study

#### Primary study design

Interventional

#### 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:

Dr Khalid A. Elmardi

National Malaria Control Programme

Federal Ministry of Health

P.O. Box 1204

Khartoum

Sudan

Tel: +249 (0)183 776809 Fax: +249 (0)183 770397

Email: khalidmrd9@hotmail.com

#### 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 µl
- 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, , BO3, 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