

# Efficacy and safety of artesunate and sulfadoxine-pyrimethamine for the treatment of uncomplicated Plasmodium falciparum malaria and chloroquine for the treatment of vivax malaria in Nangarhar, Takhar and Faryab provinces, Afghanistan

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| <b>Submission date</b><br>15/11/2007   | <b>Recruitment status</b><br>No longer recruiting        | <input checked="" type="checkbox"/> Prospectively registered |
| <b>Registration date</b><br>15/11/2007 | <b>Overall study status</b><br>Completed                 | <input type="checkbox"/> Protocol                            |
| <b>Last Edited</b><br>15/11/2007       | <b>Condition category</b><br>Infections and Infestations | <input type="checkbox"/> Statistical analysis plan           |
|  |  | <input type="checkbox"/> Results                             |
|  |  | <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

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**Contact details**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

RPC243

## **Study information**

**Scientific Title**

### **Study objectives**

Monitor efficacy and safety of artesunate and sulfadoxine-pyrimethamine for the treatment of uncomplicated Plasmodium falciparum malaria and chloroquine for the treatment of vivax malaria.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics approval received from:

1. Ministry of Public Health Afghanistan on the 15th September 2007
2. World Health Organization (WHO) Ethics Review Committee (ERC) on the 13th November 2007 (ref: RPC 243)

### **Study design**

One arm non-comparative study

### **Primary study design**

Interventional

### **Secondary study design**

Non randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Treatment

### **Participant information sheet**

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

Malaria

### **Interventions**

1. Artesunate (12 mg/kg) and sulfadoxine (25 mg/kg single dose) - pyrimethamine (1.25 mg/kg single dose) over 3 days for falciparum malaria
2. Chloroquine 25 mg/kg over 3 days for vivax malaria

**Contact details for Principal Investigator:**

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**Intervention Type**

Drug

**Phase**

Not Specified

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

Artesunate, sulfadoxine-pyrimethamine, chloroquine

**Primary outcome measure**

1. To measure the clinical and parasitological efficacy of artesunate and sulfadoxine-pyrimethamine among patients aged above six months suffering from uncomplicated falciparum malaria and chloroquine for vivax malaria, by determining the proportion of patients with:

1.1. Early Treatment Failure (ETF)

1.2. Late Clinical Failure (LTF)

1.3. Late Parasitological Failure (LPF)

1.4. Adequate Clinical and Parasitological Response (ACPR)

As indicators of efficacy

2. To differentiate recrudescences from new infections by the Polymerase Chain Reaction (PCR) analysis

3. To evaluate the incidence of adverse events

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

15/11/2007

**Completion date**

01/02/2008

**Eligibility****Key inclusion criteria**

1. Age above 6 months

2. Mono-infection with *P. falciparum* or *P. vivax*

3. Parasitaemia, 1000 - 100,000 asexual forms per µl for falciparum malaria and above 250 asexual forms per µl for vivax malaria

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

**Age group**

Child

**Lower age limit**

6 Months

**Sex**

Both

**Target number of participants**

300

**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 (see Annex 1)
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 less than 70% of the median of the National Center for Health Statistics [NCHS]/WHO normalised reference values, or who has symmetrical oedema involving at least the feet or who has a Mid Upper Arm Circumference [MUAC] less than 110 mm)
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 (e.g. cardiac, renal, hepatic diseases, Human Immunodeficiency Virus [HIV]/Acquired Immune Deficiency Syndrome [AIDS])
5. History of hypersensitivity reactions to any of the drug(s) being tested or used as alternative treatment
6. Positive pregnancy test or lactating (if adults included)

**Date of first enrolment**

15/11/2007

**Date of final enrolment**

01/02/2008

**Locations**

**Countries of recruitment**

Afghanistan

Switzerland

**Study participating centre**

## **World Health Organization**

Geneva-27  
Switzerland  
CH-1211

## **Sponsor information**

### **Organisation**

World Health Organization (WHO) (Switzerland)

### **Sponsor details**

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### **Sponsor type**

Research organisation

### **Website**

<http://www.who.int/malaria/>

### **ROR**

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

## **Funder(s)**

### **Funder type**

Research organisation

### **Funder Name**

World Health Organization (WHO) (Switzerland)

### **Alternative Name(s)**

, , Всемирная организация здравоохранения, Organisation mondiale de la Santé,  
Organización Mundial de la Salud, WHO, , ВОЗ, OMS

### **Funding Body Type**

Private sector organisation

### **Funding Body Subtype**

International organizations

**Location**

Switzerland

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration