

# Assessment of antimalarial drug efficacy in uncomplicated falciparum malaria at six sentinel sites in Pakistan

**Submission date**  
15/05/2008

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
15/05/2008

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
30/12/2020

**Condition category**  
Infections and Infestations

☐ Individual participant data

## 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

Pakistan 1

# Study information

## Scientific Title

Assessment of antimalarial drug efficacy in uncomplicated falciparum malaria at six sentinel sites in Pakistan

## Study objectives

1. To evaluate the proportion of patients with early treatment failure (ETF), late clinical failure (LTF), late parasitological failure (LPF), or with an adequate clinical and parasitological response (ACPR) as indicators of efficacy
2. To evaluate the incidence of adverse events
3. To formulate recommendations and to enable the Directorate of Malaria Control (DOMC) in the Ministry of Health to make informed decisions about the possible need for updating of the current national antimalarial treatment guidelines

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from:

1. World Health Organization (WHO) Ethics Review Committee (ERC) on the 16th January 2008 (ref: RPC254)
2. Ministry of Health (Pakistan) on the 1st December 2007 (ref: F.1-4/2003-ST)

## Study design

One arm non-blinded clinical surveillance trial

## Primary study design

Interventional

## Secondary study design

Non randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

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

Malaria

## Interventions

Artesunate 4 mg/kg/day over three days and sulfadoxine-pyrimethamine 25 mg/kg and 1.25 mg/kg single dose. The treatment is three days and the follow up is 28 days.

**Contact details for Principal Investigator:**

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**Intervention Type**

Drug

**Phase**

Not Specified

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

Artesunate, sulfadoxine-pyrimethamine

**Primary outcome measure**

1. To evaluate the proportion of patients with early treatment failure (ETF), late clinical failure (LTF), late parasitological failure (LPF), or with an adequate clinical and parasitological response (ACPR) as indicators of efficacy
2. To evaluate the incidence of adverse events

The outcome measure is at day 28 except if the patient fails or is lost to follow-up or withdrawn from the study.

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

21/01/2008

**Completion date**

06/01/2009

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

1. Aged over six months old, either sex
2. Uncomplicated mono-infection with *Plasmodium falciparum*
3. Parasitaemia, 1,000 - 100,000 asexual forms per  $\mu$ l
4. Axillary temperature greater than or equal to 37.5°C or oral/rectal temperature of greater than or equal to 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**

Other

**Sex**

Both

**Target number of participants**

300

**Key exclusion criteria**

1. Presence of general danger signs among children less than five 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 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 mothers (if adults included)

**Date of first enrolment**

21/01/2008

**Date of final enrolment**

06/01/2009

**Locations**

**Countries of recruitment**

Pakistan

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.html>

**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

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/12/2016	30/12/2020	Yes	No