

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 14/08/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/08/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 11/09/2007	Condition category 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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

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Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Artesunate, sulfadoxine-pyrimethamine, artemether-lumefantrine

Primary outcome measure

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

Secondary outcome measures

Incidence of adverse events.

Overall study start date

01/08/2007

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 μ 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

Age group

Not Specified

Sex

Not Specified

Target number of participants

180

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

Sponsor details

20 Avenue Appia
Geneva-27
Switzerland
CH-1211

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) (Sudan)

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