

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

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

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

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:

Dr Ghulam Rahim Awab

District/Phase - 4

Jalalabad City

Nangarhar

Afghanistan

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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