

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

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

No secondary outcome measures

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 μ 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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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)

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

Government organisation

Funding Body Subtype

International organizations

Location

Switzerland

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2016	30/12/2020	Yes	No