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

Submission date	Recruitment status	[_] Prospectively registered
15/05/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/05/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
30/12/2020	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Pascal Ringwald

Contact details
World Health Organization
20 Avenue Appia
Geneva-27
Switzerland
CH-1211
+41 (0)22 791 34 69
ringwaldp@who.int

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)

Primary study design
Interventional

Study design
One arm non-blinded clinical surveillance trial

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:
Dr Faisal Mansoor
23c Sabir House
Faisbad Rawalpindi
Islamabad
Pakistan
Tel: +92 (0)51 441 5494
Email: faisalmansoor100@gmail.com

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 µl
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