ISRCTN40223079 https://doi.org/10.1186/ISRCTN40223079

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

Registration date
15/11/2007

Last Edited
15/11/2007

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

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
Avenue Appia 20
Geneva-27
Switzerland
CH-1211
+41 (0)22 791 3469
ringwaldp@who.int

Additional identifiers

Protocol serial number
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)

Primary study design
Interventional

Study design
One arm non-comparative study

Study type(s)
Treatment

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
Tel: +93 (0)70 004 4853
Email: awabgr@yahoo.com

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Artesunate, sulfadoxine-pyrimethamine, chloroquine

Primary outcome(s)
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

Key secondary outcome(s)
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Months

Sex
All

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)

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, , BO3, 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