ISRCTN45665690 https://doi.org/10.1186/ISRCTN45665690

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

Registration date
15/08/2007

Last Edited
11/09/2007

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] 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

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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 µl
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
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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