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Efficacy and safety of artemether-lumefantrine for the treatment of uncomplicated Plasmodium falciparum malaria in Eritrea

Submission date	Recruitment status	[_] Prospectively registered
07/09/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/09/2007	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/10/2008	Infections and Infestations	[_] 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
RPC239; Eritrea2

Study information

Scientific Title

Study objectives
The general objective of this study is to assess the therapeutic efficacy and safety of artemether-lumefantrine for the treatment of uncomplicated P. falciparum malaria in three sentinel sites in Eritrea.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval gained from:
1. Ministry of Health Eritrea on the 18th July 2007 (ref: 15124/6716/07)
2. Research Ethics Review Committee of the World Health Organization (ERC WHO) on the 28th August 2007 (ref: RPC239)

Study design
Clinical trial, surveillance, single arm 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
Artemether and lumefantrine six doses over three days orally (per os) according to manufacturer recommendations. As this is a surveilllance study there is no control group.

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Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Artemether-lumefantrine

Primary outcome measure
To measure the clinical and parasitological efficacy (Adequate Clinical and Parasitological Response [ACPR]).

Secondary outcome measures
1. To differentiate recrudescence from new infections by the Polymerase Chain Reaction (PCR) analysis
2. To measure the clinical and parasitological efficacy PCR corrected

Overall study start date
03/09/2007

Completion date
03/03/2008

Eligibility

Key inclusion criteria
1. All ages, 6 months and above
2. Single infection with P. falciparum
3. Parasitaemia of 1,000 - 100, 000 asexual forms per µl
4. Axillary temperature of 37.5°C or oral/rectal temperature of 38°C, or history of fever in the previous 24 hours
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
Other

Sex
Both

Target number of participants

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 (SD)
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. Pregnancy or positive pregnancy test or lactating

Date of first enrolment
03/09/2007

Date of final enrolment
03/03/2008

Locations

Countries of recruitment
Eritrea

Switzerland

Study participating centre
World Health Organization
Geneva 27
Switzerland
CH-1211

Sponsor information

Organisation
World Health Organization (WHO) (Switzerland)

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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