

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

Submission date 07/09/2007	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/09/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 15/10/2008	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
20 Avenue Appia
Geneva 27
Switzerland
CH-1211
+41 (0)22 791 34 69
ringwaldp@who.int

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 surveillance study there is no control group.

Contact details of Principal Investigator:

Dr Tewolde Ghebremeskel Woldeghabir

Ministry of Health

Asmarat

P.O. Box 212

Eritrea

Tel: +291 (0)1 125 529

Fax: +291 (0)1 122 899

Email: tewoldeg@moh.gov.et or tewoldeg2003@yahoo.com

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 μ l
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)

Sponsor details

20 Avenue Appia

Geneva 27

Switzerland

CH-1211
+41 (0)22 791 34 69
ringwaldp@who.int

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