

Monitoring the efficacy and safety of artemether-lumefantrine and artesunate and amodiaquine for the treatment of uncomplicated Plasmodium falciparum malaria in Niamtougou, Sokode (Region Centrale) and Lome (Lome Commune) sentinel sites in Togo in 2007

Submission date 14/08/2007	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 15/08/2007	Overall study status Completed	☐ Protocol
Last Edited 29/09/2021	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number

RPC221

Study information

Scientific Title

Monitoring the efficacy and safety of artemether-lumefantrine and artesunate and amodiaquine for the treatment of uncomplicated Plasmodium falciparum malaria in Niamtougou, Sokode (Region Centrale) and Lome (Lome Commune) sentinel sites in Togo in 2007

Study objectives

To compare the efficacy and safety of artemether-lumefantrine and artesunate and amodiaquine in three sites in Togo.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from:

1. Ministere de la Sante du Togo on the 7th March 2007 (ref: 0109/2007/MS/CAB)
2. Ethics Review Committee of the World Health Organization (WHO) on the 11th June 2007 (ref: RPC221)

Primary study design

Interventional

Study design

Randomised open two-arm controlled study

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Malaria

Interventions

Patients will receive both of the following:

1. Artemether-lumefantrine: six doses over three days per os according to manufacturer recommendation
2. Artesunate 4 mg/kg/day for three days per os and amodiaquine 10 mg/kg/day for three days per os

Joint Sponsor:

The World Health Organisation Regional Office for Africa (WHO AFRO)

Cite du Djoue

P.O. Box 06

Brazzaville

Congo

<http://www.afro.who.int/malaria/>

Principal Investigator:
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Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Artemether-lumefantrine, artesunate, amodiaquine

Primary outcome(s)

Adequate clinical and parasitological response Polymerase Chain Reaction (PCR) corrected at day 28.

Key secondary outcome(s)

Prevalence of adverse events.

Completion date

31/10/2007

Eligibility**Key inclusion criteria**

1. Children aged 6 to 59 months old
2. Infection with *Plasmodium falciparum*
3. Parasitaemia, 2000 - 200 000 asexual forms per μ l
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

Upper age limit

59 Months

Sex

All

Total final enrolment

505

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 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

Date of first enrolment

01/07/2007

Date of final enrolment

31/10/2007

Locations

Countries of recruitment

Switzerland

Togo

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

Funder Name

The World Health Organization Regional Office for Africa (WHO AFRO) (Togo)

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	2005-2009 results	08/10/2012	29/09/2021	Yes	No