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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) sentinels sites in Togo in 2007

Submission date
14/08/2007

Registration date
15/08/2007

Last Edited
29/09/2021

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
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) sentinels 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)

Study design
Randomised open two-arm controlled study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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:
Dr Monique Dorkenoo-Agbeko
143, rue Malfakassa
Sito-Aeroport Lome
BP 7941 Lome
7829 Togo
Tel: + 228 (0)221 38 01 154
Email: monicadork@yahoo.fr

Intervention Type
Drug

Phase
Not Specified

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

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

Secondary outcome measures
Prevalence of adverse events.

Overall study start date
01/07/2007

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 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
Child

Lower age limit
6 Months

Upper age limit
59 Months

Sex
Both

Target number of participants
450

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 Syndrom [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)

Sponsor details
20 Avenue Appia
Geneva-27
Switzerland
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) (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

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

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

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