ISRCTN36463274 https://doi.org/10.1186/ISRCTN36463274

A randomised trial to assess the efficacy of arthemeter lumifantrine and dihydroartemisinin-piperquine in the treatment of uncomplicated malaria and its effects on transmission in Kenya

Submission date	Recruitment status	[X] Prospectively registered
01/02/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
01/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/01/2021	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr P Mens

Contact details
Royal Tropical Institute
Amsterdam
Netherlands
1105 AZ
+31 (0)20 566 5467
p.mens@kit.nl

Additional identifiers

Study information

Scientific Title

A randomised trial to assess the efficacy of arthemeter lumifantrine and dihydroartemisinin-piperquine in the treatment of uncomplicated malaria and its effects on transmission in Kenya

Study objectives
Find the most effective Artemisinin-based Combination Therapy (ACT) treatment for uncomplicated falciparum malaria and the best treatment in respect to the transmission of the disease.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the Kenya Medical Research institute/National Ethical Review Committee on the 16th January 2006 (SSC protocol No.: 948).

Primary study design
Interventional

Study design
Randomised, controlled, parallel group multicentre trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Malaria, Plasmodium falciparum infection

Interventions
Two groups of 75 children meeting the inclusion criteria will be enrolled to the study and randomised to a treatment with either:
1. Lumifantrine and arthemeter, or
2. Dihydroartemisinin with piperaquine.

A finger-prick blood sample for parasite detection will be taken from children presenting at the outpatient clinic with symptoms indicating uncomplicated malaria. Name of the child, father and mother, age, weight and clinical symptoms including fever are recorded at a case record form. The blood sample will be used to prepare thick and thin blood smears, and to measure haemoglobin level by using Hemocue.

Blood smears will be Giemsa-stained and parasites counted against 200 White Blood Cells (WBC), with parasite negative results based on screening of 100 microscopic fields. Parasitological data are added to the patient card.

Children diagnosed with uncomplicated P. falciparum malaria and meeting all inclusion/exclusion criteria will be enrolled in the drug study after explaining the purpose and procedures of the study and obtaining informed consent from the parent(s) or guardian(s). After enrolment, in the drug study an additional finger-prick blood sample will be taken to store a sample on filter paper for molecular testing by Quantitative Nucleic Acid Sequence Based Amplification (QT-NASBA).

All children not included in the study will be referred back to the clinician with their patient cards for further diagnosis and treatment. They will be treated as any other outpatient and receive treatment as required.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Lumifantrine and arthemeter or dihydroartemisinin with piperaquine

Primary outcome(s)
Cured from P. falciparum infection with adequate clinical and parasitological response as defined by World Health Organisation (WHO) guidelines for clinical trials in malaria research.

Key secondary outcome(s)
1. Difference in cure rate between the different treatments
2. Effect on transmission stages (gametocytes) of the parasite

Completion date
01/03/2008

Eligibility

Key inclusion criteria
1. Age six months to 12 years
2. Resident in research area and able to complete follow up
3. Temperature higher than 37.5°C but lower than 39.5°C or history of fever in last 24 hours
4. Understanding the procedures of the study by parents or guardian (informed consent)
5. Diagnosed with uncomplicated malaria (P. falciparum) only
6. Parasitaemia 100 - 100.000 parasites/ul

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Months

Upper age limit
12 Years

Sex
All

Total final enrolment
146

Key exclusion criteria
1. General danger signs, severe malaria or severe anaemia
2. Severe malnutrition
3. Presence of diseases other than malaria causing febrile conditions
4. Unwilling to participate and sign informed consent form

Date of first enrolment
01/03/2007

Date of final enrolment
01/03/2008

Locations

Countries of recruitment
Kenya

Netherlands

Study participating centre
Royal Tropical Institute
Amsterdam
Netherlands
1105 AZ

Sponsor information

Organisation
Royal Tropical Institute (KIT) (The Netherlands)

ROR
https://ror.org/01z6bgg93

Funder(s)

Funder type
Research organisation

Funder Name
Royal Tropical Institute (The Netherlands)

Results and Publications

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	results	18/11/2008	06/01/2021	Yes	No