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# 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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

### Secondary identifying numbers
N/A

# 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).

### Study design
Randomised, controlled, parallel group multicentre trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Not specified

### Study type(s)
Treatment

### Participant information sheet

### 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 measure
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.

### Secondary outcome measures
1. Difference in cure rate between the different treatments
2. Effect on transmission stages (gametocytes) of the parasite

### Overall study start date
01/03/2007

### 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

**Age group**
Child

**Lower age limit**
6 Months

**Upper age limit**
12 Years

**Sex**
Both

**Target number of participants**
150

**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)

### Sponsor details
Bio-Medical Research
Meibergdreef 39
Amsterdam
Netherlands
1105 AZ

### Sponsor type
Research organisation

### Website
http://www.kit.nl/

### ROR
https://ror.org/01z6bgg93

## Funder(s)

### Funder type
Research organisation

### Funder Name
Royal Tropical Institute (The Netherlands)

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