

Monitoring of Anti-Malarial Drug resistance by real-time quantitative nucleic acid sequence-based amplification and the impact on TRANSMission of Plasmodium falciparum

Submission date 31/10/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/03/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 26/08/2021	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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Monitoring of Anti-Malarial Drug resistance by real-time quantitative nucleic acid sequence-based amplification and the impact on TRANSMission of Plasmodium falciparum

Acronym

AMD-TRANS

Study objectives

Firstline anti-malarial drugs can have a different impact on transmission of Plasmodium falciparum. Few studies have directly addressed this issue and frequently used microscopical detection of gametocytes as an endpoint. In the current proposal we use a molecular gametocyte detection technique to detect gametocytes and study post-treatment infectiousness to mosquitoes in an experiment set-up.

Hypothesis: submicroscopic gametocytaemia is common before and after treatment and the use of artesunate will reduce post-treatment malaria transmission.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval received from the Kenya Medical Research Institute on the 15th July 2004 (ref: SSC no. 791, KEMRI/RES/7/3/1).

Study design

Randomised single blind drug study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Screening

Participant information sheet

Health condition(s) or problem(s) studied

Uncomplicated febrile malaria

Interventions

Participants will be randomised to treatment with:

1. Sulphadoxine (25 mg/kg) and pyrimethamine (1.25 mg/kg) as a single dose plus placebo once daily for three days
2. SP plus Artesunate (AS), 4 mg/kg once daily for three days
3. SP plus Amodiaquine (AQ), 10 mg/kg once daily for three days
4. Artemether-Lumefantrine, administered as oral tablet (20 mg artemether, 120 mg lumefantrine) per 5 kg body weight in the six-dose regimen: at enrolment and eight, 20, 32, 44, 56 hours (90 min) after the initiation of treatment

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Sulphadoxine, pyrimethamine, artesunate, amodiaquine and artemether-lumefantrine.

Primary outcome measure

The following are assessed on days one, two, three, seven, 14 and 28 after initiation of treatment:

1. Resolution of clinical symptoms
2. Presence of malaria parasites by microscopy and molecular techniques
3. Presence of sexual stage malaria parasites by microscopy and molecular techniques
4. Haematological recovery

On day 14 the infectiousness to mosquitoes will be assessed by taking a small venous blood sample (2 mL) from children aged less than two years for membrane feeding assays. The blood sample will be offered to locally reared mosquitoes through a membrane. The number of infected mosquitoes and the number of oocysts in infected mosquitoes are primary outcomes for this part of the study.

Secondary outcome measures

1. Selection of drug-resistant parasite strains after treatment
2. Transmission of drug-resistant parasite strains after treatment

Overall study start date

01/09/2004

Completion date

31/12/2004

Eligibility

Key inclusion criteria

1. Age six months to ten years
2. Residents of research area, able to come for complete schedule of follow-up
3. Diagnosed with uncomplicated malaria, *Plasmodium falciparum* or *P. falciparum* and *P. malariae* double infection
4. Parasitaemia 1000 to 100,000 *P. falciparum* P/ul (Giemsa-stained blood smears counted

against 200 White Blood Cells (WBC), negative result if 100 parasite negative microscopic fields)
5. Temperature more than 37.5°C and less than 39.5°C, or a history of fever in the previous 24 hours
6. No history of adverse reactions to Sulphadoxine-Pyrimethamine (SP) treatment
7. Understanding of the procedures of the study by parent or guardian and willing to participate (informed consent signed)

Participant type(s)

Patient

Age group

Child

Lower age limit

6 Months

Upper age limit

10 Years

Sex

Not Specified

Target number of participants

500

Key exclusion criteria

1. General danger signs of severe malaria or Haemoglobin (Hb) count more than 5 gm/dl
2. Severe malnutrition
3. Presence of diseases other than malaria causing febrile conditions
4. Unwilling to participate and sign informed consent forms

Date of first enrolment

01/09/2004

Date of final enrolment

31/12/2004

Locations**Countries of recruitment**

Kenya

Netherlands

Study participating centre

Radboud University Nijmegen Medical Centre

Nijmegen

Netherlands

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Sponsor information

Organisation

The Netherlands Foundation for the Advancement of Tropical Research (NWO-WOTRO) (The Netherlands)

Sponsor details

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Sponsor type

Research organisation

Website

http://www.nwo.nl/nwohome.nsf/pages/NWOA_6UB9S8_Eng

ROR

<https://ror.org/04jsz6e67>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Foundation for the Advancement of Tropical Research (NWO-WOTRO) (The Netherlands) (ref: 2003/00702)

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