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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 27/03/2007	**Overall study status** Completed	
Last Edited 26/08/2021	**Condition category** 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
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
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Sponsor information

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

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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