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The GAMetocyticidal activity of sulphadoxine-pyremthamine plus artesunate followed by a single dose of PrimaQuine

Submission date	Recruitment status	[_] Prospectively registered
31/10/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/12/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
16/04/2010	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

Protocol serial number
N/A

Study information

Scientific Title
The activity of sulphadoxine-pyrimethamine plus artesunate (SP+AS) and SP+AS followed by a single dose of primaquine (0.75 mg/kg) against gametocytes in Tanzanian children with uncomplicated falciparum malaria

Acronym
GAM-PQ

Study objectives
Gametocytocidal drugs can play an important role in malaria control. The current study proposal is a pilot study to determine the efficacy of a gametocytocidal drug combination that consists of the extensively tested combination of Sulphadoxine-Pyrimethamine (SP) plus Artesunate (AS), followed by a single dose of Primaquine (PQ). This combination has previously been used and has been shown to be safe and efficient in clearing microscopic gametocytes. In this study we propose to confirm the safety in a Tanzanian population and to determine the added value of a single dose of PQ on the clearance of (sub-microscopic) gametocytes compared to SP and AS alone.

Hypothesis: Primaquine adds to the gametocyticidal effect of artesunate and clears sub-microscopic gametocytes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. London School of Hygiene & Tropical Medicine - 24th July 2006 (ref: 4097)
2. National Insititue of Medical Research, Tanzania - 21st June 2006 (ref: NIMR/HQ/R.8A Vol.XIII /446)

Study design
Randomised single blind drug study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Uncomplicated febrile malaria

Interventions
Participants will be randomised to treatment with:
1. Sulfadoxine-pyrimethamine (SP) (500 mg S; 25 mg P/20 kg body weight, day zero) and artesunate (4 mg/kg, day zero, one, two) followed by a placebo (day two)
2. SP (500 mg S; 25 mg P/20 kg body weight, day zero) and AS (4 mg/kg, day zero, one, two) followed by primaquine (PQ) (0.75mg/kg, day two)

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Sulphadoxine-pyrimethamine, artesunate and primaquine

Primary outcome(s)
The following are assesed on days one, two, three, seven, 14, 28 and 42 after treatment:
1. Resolution of clinical symptoms
2. Haematological recovery
3. Presense of malaria parasites by microscopy and molecular technicques
4. Presence of sexual stage parasites by microscopy and molecular technicques

Key secondary outcome(s))
1. Haematological recovery in G6PD deficient and non deficient individuals
2. Selection of drug-resistant parasite strains after treatment

Completion date
13/10/2006

Eligibility

Key inclusion criteria
1. Age more than three years
2. Residents of research area (5 km around the clinic)
3. Willingness to come for complete scheduled follow-up
4. Uncomplicated malaria with Plasmodium falciparum mono-infection
5. Parasitaemia of 500,000 to 900,000 parasites/ul
6. Temperature more than 37.5 and less than 39.5°C, or history of fever in the previous 24 hours
7. No history of adverse reactions to SP or PQ treatment
8. Understanding of the procedures of the study by parent or guardian and willing to participate by signing informed consent forms

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Other

Sex
All

Key exclusion criteria
1. General signs of severe malaria or haemoglobin count less than 8 g/dl
2. Presence of disease other than malaria causing febrile conditions
3. Unwilling to participate and sign informed consent forms
4. Eligibility for (or participation in) other malaria projects in the Korogwe area, notably the Intermittent Preventive Treatment of malaria in infants (IPTi) study

Date of first enrolment
01/08/2006

Date of final enrolment
13/10/2006

Locations

Countries of recruitment
Tanzania

Study participating centre
Joint Malaria Programme
Moshi
Tanzania
Box 2228

Sponsor information

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

ROR
https://ror.org/04jsz6e67

Funder(s)

Funder type
Research organisation

Funder Name
The Netherlands Foundation for the Advancement of Tropical Research (NWO-WOTRO) (Netherlands) - Poverty Related Infection Oriented Research (PRIOR) (ref: WIZ93-465)

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	10/10/2007		Yes	No