

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

Submission date 31/10/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 04/12/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 16/04/2010	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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 gametocytocidal 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 Institute 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 assessed on days one, two, three, seven, 14, 28 and 42 after treatment:

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

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				

[Results article](#)

10/10/2007

Yes

No