

Measuring malaria transmission after drug treatment

Submission date 31/01/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 22/07/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 04/02/2016	Condition category Infections and Infestations	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Malaria is a serious tropical disease spread by mosquitoes. Previous studies monitoring the success of drug treatment in curing malaria in African children had found that drugs differed in whether the cured children were prevented from passing on malaria to mosquitoes. With the new generation of combination drugs becoming widely available in the early 2000s we sought to compare these with the older drugs, and to test whether these were more effective at not only curing the disease, but in preventing further mosquito infections.

Who can participate?

Children under 12 years of age who were brought to the Farafenni hospital, in The Gambia, for malaria treatment.

What does the study involve?

The children are randomly allocated to one of the study medications, and sent home with all the drugs they would need. Our health worker team then visits each child at home (by motorbike) on subsequent days to assist with the continuing treatment, and to monitor the cure by taking small finger-prick blood samples to test for persisting parasites. Seven days after treatment the children are brought in to the study clinic and lab for a thorough check, and those with any potentially infectious parasites in their blood after checking under the microscope are asked to give an additional blood sample. This sample is then used to experimentally feed mosquitoes to check whether this child is still potentially infectious to the insects which spread malaria.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

Farafenni hospital in The Gambia

When is the study starting and how long is it expected to run for?

January 2000 to December 2003

Who is funding the study?
The Wellcome Trust and MRC Laboratories (UK)

Who is the main contact?
Dr Colin Sutherland
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
061910

Study information

Scientific Title
The impact of anti-malarial treatment upon the development and persistence of Plasmodium falciparum gametocytes in vitro and in vivo

Study objectives
That use of artemisinin combination chemotherapy for treating uncomplicated falciparum malaria in children will reduce transmissibility of malaria to mosquitoes, compared to other combinations or to monotherapies.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. LSHTM Ethics Committee, 05/09/2000, ref: 708
2. Joint Gambia Government/MRC Laboratories Ethics Committee, 06/08/2000, ref: SCC/EC 838 /798. Approved annually on 20/09/2001 (ref: SCC/EC 887/844) and 14/08/2002 (ref: SCC/EC 910)

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Malaria

Interventions

Combination antimalarial therapy versus established monotherapy. Single-blind open-label randomised controlled trial run over three consecutive transmission seasons in Farafenni, The Gambia.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Artemisinin combination chemotherapy

Primary outcome(s)

Major endpoints were:

1. Post-treatment gametocyte carriage over 28 days
2. Infectiousness to mosquitoes of children carrying gametocytes seven days after treatment

Key secondary outcome(s))

Minor endpoints were:

1. Clinical and parasitological drug efficacy over 28 days of follow-up

Completion date

31/12/2003

Eligibility

Key inclusion criteria

1. Children one to ten years of age (either sex) attending Farafenni Health Centre, The Gambia, from September to December in each of 2000, 2001 and 2002
2. Children with a temperature more than 37.5°C, or a history of fever
3. Blood-film positive for *P. falciparum* at a density greater than 500 parasites per ml
4. Signed informed consent was obtained

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

1 years

Upper age limit

10 years

Sex

All

Key exclusion criteria

1. An inability to take drugs orally
2. Treatment with antimalarial chemotherapy within the past two weeks
3. Carriage of circulating gametocytes at presentation
4. Any evidence of chronic disease or acute infection other than malaria
5. Domicile outside the study area (approximately 10 km radius)
6. Any signs or symptoms of severe malaria:
 - 6.1. Severe anaemia (peripheral blood Packed Cell Volume [PCV] less than 20%)
 - 6.2. Hyper-parasitaemia (more than 250,000 per ml peripheral blood)
 - 6.3. Respiratory distress (respiratory rate more than 40 with two of the following: nasal flaring, intercostal indrawing, subcostal recession or grunting)
 - 6.4. Repeated generalised convulsions (three or more per 24 hours or two witnessed seizures in 24 hours)
 - 6.5. Haemoglobinuria (dark red/black urine)
 - 6.6. Jaundice
 - 6.7. Prostration
 - 6.8. Circulatory collapse

Date of first enrolment

01/01/2000

Date of final enrolment

31/12/2003

Locations

Countries of recruitment

United Kingdom

England

Gambia

Study participating centre

London School of Hygiene & Tropical Medicine
London
United Kingdom
WC1E 7HT

Sponsor information

Organisation

London School of Hygiene and Tropical Medicine (UK)

ROR

<https://ror.org/00a0jsq62>

Funder(s)

Funder type

Charity

Funder Name

The Wellcome Trust (UK) (grant ref: 061910)

Funder Name

MRC Laboratories (The Gambia) - Scientific Coordinating Committee (Projects: 838, 887 and 910)

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	01/12/2002		Yes	No
Results article	results	01/07/2003		Yes	No
Results article	results	01/01/2004		Yes	No

Results article	results	01/10/2004	Yes	No
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Results article	results	28/05/2008	Yes	No
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