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Measuring malaria transmission after drug treatment

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

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

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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)

Primary study design

Interventional

Study design
Randomised controlled trial

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
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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
Results article	results	28/05/2008	Yes	No