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A randomised study of Agent A with Agent B against Agent C in the treatment of non-severe Plasmodium falciparum malaria

Submission date	Recruitment status	[_] Prospectively registered
12/09/2003	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/09/2003	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
25/04/2014	Infections and Infestations	[_] Record updated in last year

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
N0263115165

Study information

Scientific Title

Study objectives
Is Agent A better treatment than Agent B for patients with mild moderate falciparum malaria?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Infections and Infestations: Malaria

Interventions
Randomised controlled trial:
A. Quinine and Fabsidar
B. Malarone

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Quinine, Fabsidar, Malarone

Primary outcome measure

1. Time to full recovery
2. Side effects of treatment
3. Relapse of malaria.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2002

Completion date
01/07/2006

Eligibility

Key inclusion criteria
400 Patients from Infectious/Tropical Diseases.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
400

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/07/2002

Date of final enrolment
01/07/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Hospital for Tropical Diseases
London
United Kingdom
WC1E 6JD

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Government

Funder Name
University College London Hospitals NHS Trust (UK)

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