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A phase III, randomised, non-inferiority trial, to assess the efficacy and safety of Dihydroartemisinin and Piperaquine (DHA + PPQ, Artekin®) in comparison with Artemether and Lumefantrine (A + L, Coartem®) in children with uncomplicated Plasmodium falciparum malaria

Submission date 21/03/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/05/2005	**Overall study status** Completed	
Last Edited 25/08/2011	**Condition category** 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
ST3073+ST3074 DM040011

Study information

Scientific Title

Study objectives
The primary objective of the study is to measure the Day 28, PCR corrected cure rates of Artekin and Coartem and demonstrate that:
1. The cure rate of Artekin is non-inferior to that of Coartem (non-inferiority margin = 5%)
2. The cure rate of Artekin is at least 90%.
This cure rate is defined as the proportion of patients with adequate clinical and parasitological response at Day 28.

Ethics approval required
Old ethics approval format

Ethics approval(s)
No ethics information provided at time of registration.

Primary study design
Interventional

Study design
Phase III, randomised, non-inferiority trial

Study type(s)
Not Specified

Health condition(s) or problem(s) studied
Malaria

Interventions
Dihydroartemisinin + Piperaquine (DHA + PPQ, Artekin ®) tablets containing 20 mg or 40 mg of Dihydroartemisinin and 160 mg or 320 mg of Piperaquine in comparison with Artemether + Lumefantrine (A + L, Coartem ®) tablets containing 20 mg of Artemether and 120 mg of Lumefantrine.

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Dihydroartemisinin, Piperaquine, Artemether and Lumefantrine

Primary outcome(s)
The Day 28, Polymerase Chain Reaction (PCR) corrected cure rates of Artekin and Coartem.

Key secondary outcome(s)
1. Comparison of the uncorrected Day 28 cure rates of both drugs
2. Comparison of the safety profiles of the two treatments
3. Comparison of times of parasite clearance
4. Comparison of time of fever clearance
5. Comparison of gametocytes (prevalences and densities)
6. Comparison of haemoglobin (Hb) changes from day zero to day 28
7. Comparison of cure rates at D42 (PCR corrected and uncorrected)

Completion date
01/05/2006

Eligibility

Key inclusion criteria
1. Males and Females aged between six months and 59 months inclusive
2. Body weight at least 5 kg
3. Microscopically confirmed, monoinfection of Plasmodium falciparum
4. History of fever or presence of fever (axillary temperature at more than or equal to 37.5°C)
5. Written informed consent.
6. 1500 patients (1000 DHA + PPQ; 500 A + L)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Months

Upper age limit
59 Months

Sex
All

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/05/2005

Date of final enrolment
01/05/2006

Locations

Countries of recruitment
Belgium

Burkina Faso

Kenya

Mozambique

Uganda

Zambia

Study participating centre
Prince Leopold Institut of Tropical Medicine
Antwerp
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B-2000

Sponsor information

Organisation
Sigma-Tau (Italy)

ROR
https://ror.org/03bxtpd68

Funder(s)

Funder type
Charity

Funder Name
Medicines for Malaria Venture (MMV)

Alternative Name(s)
MMV

Funding Body Type
Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location
Switzerland

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	17/11/2009		Yes	No