ISRCTN16263443 https://doi.org/10.1186/ISRCTN16263443

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

Registration date
05/05/2005

Last Edited
25/08/2011

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
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.

Study design
Phase III, randomised, non-inferiority trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Secondary outcome measures
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)

Overall study start date
01/05/2005

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

Age group
Child

Lower age limit

6 Months

Upper age limit
59 Months

Sex
Both

Target number of participants
1500

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
Belgium
B-2000

Sponsor information

Organisation
Sigma-Tau (Italy)

Sponsor details
Industrie Farmaceutiche Riunite, SpA
via Pontina Km. 30,400
Pomezia (Rome)
Italy
00040

Sponsor type
Industry

Website
http://home.sigma-tau.it/

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	17/11/2009		Yes	No