

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

Registration date
05/05/2005

Overall study status
Completed

Last Edited
25/08/2011

Condition category
Infections and Infestations

- ☐ Prospectively registered
- ☐ Protocol
- ☐ Statistical analysis plan
- ☒ Results
- ☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Umberto D'Alessandro

Contact details
Prince Leopold Institut of Tropical Medicine
Nationalestraat 155
Antwerp
Belgium
B-2000

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 Artekina and Coartem and demonstrate that:

1. The cure rate of Artekina is non-inferior to that of Coartem (non-inferiority margin = 5%)
2. The cure rate of Artekina 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

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Malaria

Interventions

Dihydroartemisinin + Piperaquine (DHA + PPQ, Artekina ®) 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 Artekina 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

Belgium

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