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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 artesunate and mefloquine (AS + MQ) in patients affected by acute, uncomplicated Plasmodium falciparum malaria

Submission date
21/03/2005

Registration date
05/05/2005

Last Edited
25/07/2012

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 DM040010

Study information

Scientific Title

Study objectives
The primary objective of the study is to measure the Day 63, polymerase chain reaction (PCR) corrected cure rates of artekin and AS + MQ and demonstrate that:
1. The cure rate of Artekin is non-inferior to that of AS + MQ (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 63 plus those treatment failures identified as new infection by PCR.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not 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

Randomisation will stratify infants, children and adults by age. Patients randomised to:
1. Tablets containing 40 mg of dihydroartemisinin and 320 mg of piperaquine for adult patients or containing 20 mg of dihydroartemisinin and 160 mg of piperaquine for infants and children
2. Tablets containing 50 mg of artesunate and tablets containing 250 mg of mefloquine

Intervention Type
Drug

Phase
Phase III

Drug/device/biological/vaccine name(s)
Dihydroartemisinin + Piperaquine (DHA + PPQ, Artekin®) in comparison with Artesunate + Mefloquine (AS + MQ)

Primary outcome measure
The Day 63, PCR corrected cure rates of artekin and AS+MQ

Secondary outcome measures
1. The comparison of the uncorrected Day 63 cure rates of both drugs (also known as adequate clinical and parasitological response [ACPR])
2. The comparison of the amount of overall treatment failure
3. The comparison of the safety profiles of the two treatments
4. Proportion of patients with treatment failure (TF)
5. Proportion of aparasitaemic patients
6. Proportion of afebrile patients
7. Gametocytes carriage
8. Fractional change in haemoglobin/haematocrit

Overall study start date
01/01/2000

Completion date
01/01/2001

Eligibility

Key inclusion criteria
1. Males and females aged between three months and 65 years inclusive
2. Body weight at least 5 kg
3. Microscopically confirmed, monoinfection of Plasmodium falciparum or mixed infection
4. History of fever or presence of fever (tympanic temperature at more than or equal to 37.5°C)
5. Written informed consent
6. 1050 patients (700 DHA + PPQ; 350 AS + MQ)

Participant type(s)
Patient

Age group
Not Specified

Sex
Both

Target number of participants
1050

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2000

Date of final enrolment
01/01/2001

Locations

Countries of recruitment
India

Lao People's Democratic Republic

Thailand

Study participating centre
Wellcome Trust Southeast Asian Tropical Medicine Research Units
Bangkok
Thailand
10400

Sponsor information

Organisation
Sigma-Tau (Italy)

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

Sponsor type
Industry

ROR
https://ror.org/03bxtpd68

Funder(s)

Funder type
Charity

Funder Name
Medicines for Malaria Venture (MMV) (Switzerland)

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	30/07/2010		Yes	No
Results article	results from India	20/07/2012		Yes	No