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Open-label randomised clinical trial of pharmacokinetics, efficacy, and tolerability of the fixed-dose artesunate/amodiaquine combination therapy versus both drugs administered separately for treatment of uncomplicated falciparum malaria in Kenya

Submission date
05/07/2007

Recruitment status
No longer recruiting

Registration date
21/08/2007

Overall study status
Completed

Last Edited
28/03/2017

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

Protocol serial number
1199

Study information

Scientific Title
Open-label randomised clinical trial of pharmacokinetics, efficacy, and tolerability of the fixed-dose artesunate/amodiaquine combination therapy versus both drugs administered separately for treatment of uncomplicated falciparum malaria in Kenya

Study objectives
1. To investigate pharmacokinetic parameters of the fixed-dose artesunate/amodiaquine (AS /AQ) combination in adults with comparison to separate administration of the two drugs using a population pharmacokinetic design
2. To measure the clinical and parasitological efficacy of the fixed-dose AS/AQ combination therapy
3. To measure the parasite reduction ratio at 48 hours of treatment, parasite and fever clearance rates, proportions of patients with gametocyte persistence during follow up
4. To evaluate the incidence of adverse events
5. To formulate recommendations and to enable the Kenyan Ministry of Health to make informed decisions about the possible need for updating of the current national antimalarial treatment guidelines

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of the Kenya Medical Research Institute, 22/05/2007

Primary study design
Interventional

Study design
Open-label randomised single-centre clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Uncomplicated falciparum malaria

Interventions
Patients will be equally randomised into the following treatment groups:
Group A: fixed-dose AS/AQ combination tablets (100 mg/270 mg), two tablets once daily for three consecutive days.
Group B: AS tablets (50 mg): four tablets once a day for three consecutive days, and AQ tablets (153 mg): four tablets once a day for three consecutive days.

Patients will be followed-up for 28 days, and the total follow-up for the study will be 9 months.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Artesunate, amodiaquine

Primary outcome(s)
The primary objective of this study is to investigate the pharmacokinetic properties of fixed-dose combination AS/AQ. Blood sampling will be performed at predefined time points in both groups of patients. The evaluation of pharmacokinetics variables will take place over the three-day treatment and the entire follow-up off-treatment.

Key secondary outcome(s)
1. Treatment outcomes: the classification of treatment outcomes will be based on an assessment of the parasitological and clinical outcome of antimalarial treatment according to the latest (2005) guidelines of World Health Organisation (WHO). Accordingly, all patients will be classified as having an Early Treatment Failure, a Late Clinical Failure, a Late Parasitological Failure, or an Adequate Clinical and Parasitological Response
2. Safety variables: the occurrence of any adverse event will be documented. All patients will be routinely asked about old symptoms and new symptoms emerging since previous visit during follow-up

Completion date
30/03/2008

Eligibility

Key inclusion criteria
1. Adults from 18 to 60 years of age; either gender
2. Presenting with acute uncomplicated falciparum malaria:
2.1. Oral temperature greater than 37.5°C, or
2.2. History of fever in the last 24 hours
3. Positive P. falciparum parasitaemia (greater than 1000 asexual parasites/µL)
4. Written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Any other concomitant febrile illness, e.g. upper respiratory tract infection or Ear, Nose and Throat (ENT) infection
2. Features of severe malaria
3. Mixed Plasmodium infection

Date of first enrolment
09/07/2007

Date of final enrolment
30/03/2008

Locations

Countries of recruitment
Kenya

Study participating centre
Walter Reed Project
Kisumu
Kenya
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Sponsor information

Organisation
Drugs for Neglected Diseases initiative (DNDi) (Switzerland)

ROR
https://ror.org/022mz6y25

Funder(s)

Funder type
Research organisation

Funder Name
Drugs for Neglected Diseases initiative (DNDi) (Switzerland)

Funder Name

Ministerie van Buitenlandse Zaken

Alternative Name(s)
Dutch Ministry of Foreign Affairs, Ministry of Foreign Affairs, Ministry of Foreign Affairs of the Kingdom of the Netherlands

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Netherlands

Funder Name
Medecins Sans Frontieres (MSF) (International)

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	01/06/2010		Yes	No