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Multicentre, open-label randomised clinical trial of efficacy and tolerability of the fixed-dose artesunate/amodiaquine (AS/AQ) combination therapy and amodiaquine (AQ) monotherapy for treatment of uncomplicated falciparum malaria in India

Submission date 15/01/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/01/2008	**Overall study status** Completed	
Last Edited 28/03/2017	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DND-ASQ-06

Study information

Scientific Title
Multicentre, open-label randomised clinical trial of efficacy and tolerability of the fixed-dose artesunate/amodiaquine (AS/AQ) combination therapy and amodiaquine (AQ) monotherapy for treatment of uncomplicated falciparum malaria in India

Study objectives
1. To measure the clinical and parasitological efficacy of the fixed-dose artesunate/amodiaquine combination therapy among children and adults patients (6-month to 60-year old) suffering from uncomplicated falciparum malaria, by determining the proportion of patients achieving a negative parasitaemia without relapse before 28 days (cure rate)
2. To measure the parasite reduction ratio at 48 hours of treatment, parasite clearance time, fever clearance time, proportion of patients with gametocyte persistence at end-of-treatment
3. To evaluate the incidence of adverse events
4. To formulate recommendations and to enable the 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)
Institutional Ethics Committee of the National Institute of Malaria Research (ICMR), 26/09/2006

Study design
Multicentre open-label randomised clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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

Interventions
Patients will be randomised into the following treatment groups (2:1):
Group A: fixed-dose AS/AQ combination tablets (paediatric: 25 mg/67.5 mg - adult: 100 mg/270 mg), oral route, dose according to age, once-daily during three days
Group B: AQ tablets, oral route, dose according to age, three-day course

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Cure rate: proportion of patients with 'Adequate Clinical and Parasitological Response' (ACPR) as defined by WHO

Secondary outcome measures
Secondary efficacy endpoints:
1. Parasite reduction ratio (PRR) at 48 hours
2. Parasite clearance time
3. Fever clearance time
4. Proportion of patients with gametocytes persistence at end-of-treatment
5. Proportion of patients with early treatment failure (ETF), late treatment failure (LTF), and late parasitological failure (LPF)

Safety variables:
Incidence of any adverse event will be documented. All patients will be routinely asked about old symptoms and new symptoms emerging since previous visit

Overall study start date
01/02/2007

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Children and adults from 6 months to 60 years of age, both genders
2. For children: body weight greater than 5 kg
3. Uncomplicated falciparum malaria
4. Axillary temperature greater than 37.5°C
5. P. falciparum parasitaemia 1000 - 100,000 asexual forms/µL
6. Ability to swallow oral medication
7. Ability and willingness to comply with the study protocol for the duration of the study and to comply with the study visit schedule
8. Written informed consent (participant or parent/guardian)

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
300 patients

Key exclusion criteria
1. Presence of general danger signs among the children less than 5 years old or other signs of severe and complicated falciparum malaria according to current World Health Organization (WHO) definitions
2. Mixed or mono-infection with another Plasmodium species
3. Presence of severe malnutrition
4. Presence of febrile conditions due to diseases other than malaria (measles, acute lower tract respiratory infection, severe diarrhoea with dehydration, etc.) or other known underlying chronic or severe disease (e.g. cardiac, renal, hepatic diseases, human immunodeficiency virus [HIV] /acquired immune deficiency syndrome [AIDS])
5. History of hypersensitivity reactions to any of the drug(s) being tested or used as alternative treatment
6. Positive pregnancy test or lactating
7. H/O antimalarial treatment in past 15 days

Date of first enrolment
01/02/2007

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
India

Study participating centre
National Institute of Malaria Research
New Delhi
India
110029

Sponsor information

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

Sponsor details
15 Chemin Louis Dunant
Geneva
Switzerland
CH-1202

Sponsor type
Research organisation

Website
http://www.dndi.org/

ROR
https://ror.org/022mz6y25

Funder(s)

Funder type
Research organisation

Funder Name
Medecins Sans Frontieres (MSF) (International)

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

Department for International Development

Alternative Name(s)
Department for International Development, UK, DFID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	30/03/2012		Yes	No