ISRCTN22508774 https://doi.org/10.1186/ISRCTN22508774

A single dose two-phase crossover study to assess the tolerability and pharmacokinetic parameters of a fixed dose formulation of artesunate-mefloquine and standard dose artesunate and mefloquine as loose tablets in healthy normal volunteers (Thailand)

Submission date
12/09/2005

Recruitment status
No longer recruiting

Registration date
01/02/2006

Overall study status
Completed

Last Edited
28/03/2017

Condition category
Other

[_] 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

Contact name
Dr W Taylor

Contact details
20, Avenue Appia
Geneva-27
Switzerland
CH 1211
-
taylorw@who.int

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RPC117

Study information

Scientific Title
A single dose two-phase crossover study to assess the tolerability and pharmacokinetic parameters of a fixed dose formulation of artesunate-mefloquine and standard dose artesunate and mefloquine as loose tablets in healthy normal volunteers (Thailand)

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Received from the local medical ethics committee on 27/05/2005

Study design
Single dose two-phase crossover study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Not specified

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
Pharmacokinetics of drug

Interventions
Two tablets of fixed dose artesunate and mefloquine, given once: total dose = AS 200mg, MQ 400 mg.

Loose tablets - 200 mg of artesunate (4 tablets) and 500 mg of mefloquine (2 tablets).

Intervention Type

Drug

Phase
Not Applicable

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

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
25/02/2005

Completion date
25/02/2006

Eligibility

Key inclusion criteria
1. Age 18 to 50 years
2. Written consent given after reading the volunteer information leaflet. Participation must be voluntary and volunteers will be fully informed of possible side effects. They will be informed that they are free to withdraw at any time
3. No significant abnormal findings on history or examination, particularly no prior liver disease, cardiovascular disease (including arrythmias), peripheral neuropathy, convulsions, and psychiatric disease
4. No clinically significant abnormalities on:
4.1. Haematology:
4.1.1. Haemoglobin: male 13.6 - 17.5 g/dl, female 12 - 15.5 g/dl
4.1.2. Total white cell count: 4 - 10 x 10^3/ul
4.1.3. Platelet counts: 150 - 450 x 10^3/ul
4.2. Liver:
4.2.1. Total bilirubin less than 1.2 mg/dl
4.2.2. Serum Glutamic Oxaloacetic Transaminase (SGOT) less than or equal to 35 IU/l
4.2.3. Serum Glutamic Pyruvic Transaminase (SGPT) less than or equal to 35 IU/l
4.3. Renal function:
4.3.1. Creatinine 50 - 100 umol/l
4.3.2. Blood urea nitrogen 8 - 20 mg/dl
5. Negative pregnancy test (women) using the urine beta Human Chorionic Gonadotropin (βHCG)
6. Normal electrocardiogram (physicians reading: running at 50 mm/sec)
7. No history of antimalarial ingestion (chloroquine, amodiaquine, quinine, halofantrine, pyrimethamine-sulfadoxine) in the preceding two months, and for mefloquine, preceding three months
8. No other drugs or medications, including over-the counter preparations, ingested in the preceding week
9. Adequate venous access
10. Not participating in another clinical trial

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
1. Refusal of consent
2. Clinically significant physical signs detected by the examining physician
3. Abnormal electrocardiogram detected by the examining physician
4. Presence of hepatic, renal and gastrointestinal disorders
5. Smokers (greater than 10 cigarettes/day), abuse of alcohol or recreational drugs
6. Presence of malaria parasites on a thick smear
7. Subjects having been in a malarial area in the preceding eight weeks
8. Subjects having ingested drugs in the preceding week
9. Presence of acute or chronic infections
10. Allergy to study drugs

Date of first enrolment
25/02/2005

Date of final enrolment
25/02/2006

Locations

Countries of recruitment
Switzerland

Thailand

Study participating centre
20, Avenue Appia
Geneva-27
Switzerland
CH 1211

Sponsor information

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

Sponsor details
15 Chemin Louis Dunant
Geneva
Switzerland
CH 1202
+41 (0)22 906 9230
dndi@dndi.org

Sponsor type
Research organisation

Website
http://www.dndi.org

ROR
https://ror.org/022mz6y25

Funder(s)

Funder type
Research organisation

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

Funder Name
Confirming the International Role of Community Research for Development - Developing Countries (INCO-DEV)

Funder Name
European Commission (ref: ICA4-2001-10193)

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκής Επιτροπής, Европейската комисия, Evropské komise, Commission européenne, Choimisiúin Eorpaigh, Europskoj komisiji, Commissione europea, La Commissione

europea, Eiropas Komisiju, Europos Komisijos, Európai Bizottságról, Europese Commissie, Komisja Europejska, Comissão Europeia, Comisia Europeană, Európskej komisii, Evropski komisiji, Euroopan komission, Europeiska kommissionen, EC, EU

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Funder Name
United Nations Children's Fund (UNICEF)/United Nations Development Programme (UNDP) /World Bank/World Health Organization (WHO) - Special Programme for Research and Training in Tropical Diseases (TDR)

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	01/06/2010		Yes	No