ISRCTN70132716 https://doi.org/10.1186/ISRCTN70132716

Artesunate and Amodiaquine: tolerability and pharmacokinetic study in healthy normal volunteers of non-fixed and fixed combination (Malaysia)

Submission date
15/04/2005

Recruitment status
No longer recruiting

Registration date
07/06/2005

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

Contact name
Dr W Taylor

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

Additional identifiers

Protocol serial number
RPC112

Study information

Scientific Title

Artesunate and Amodiaquine: tolerability and pharmacokinetic study in healthy normal volunteers of non-fixed and fixed combination (Malaysia)

Study objectives
Not provided at time of registration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Artesunate tablet 50 mg. Amodiaquine tablet (153 mg base/tablet).
Combination of artesunate/amodiaquine (100 mg and 270 mg, respectively).
For both arms, a single dose of appropriate drug(s) will be taken orally with 200 ml tap water after an overnight fast.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s))
Not provided at time of registration

Completion date
26/11/2006

Eligibility

Key inclusion criteria
1. Male/female age 21 - 45 years
2. Written consent
3. Voluntary participation fully aware of possible side effects
4. No significant abnormal findings on history or examination, particularly no prior liver disease, cardiovascular disease or peripheral neuropathy
5. No clinically significant abnormalities on haematology, liver and renal function tests
6. Non pregnant on test (women)
7. Normal electrocardiogram (ECG)
8. No history of antimalarial ingestion (chloroquine, amodiaquine, quinine, halofantrine, pyrimethamine-sulfadoxine associated or not to mefloquine) in the preceding two months
9. No other drugs or medications, including over-the-counter preparations, ingested in the preceding week
10. Adequate venous access

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Refusal of consent
2. Biological or electrocardiographic anomalies
3. Presence of hepatic, renal and gastrointestinal disorders
4. Smokers (>10/day), abuse of alcohol or recreational drugs
5. Presence of malaria parasites on a thick smear
6. Subjects having been in a malarial area in the preceding 8 weeks
7. Subjects having ingested drugs in the preceding week
8. Presence of acute or chronic infections

Date of first enrolment
26/11/2004

Date of final enrolment
26/11/2006

Locations

Countries of recruitment
Malaysia

Switzerland

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

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
European Commission

Alternative Name(s)
European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, 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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2009		Yes	No