

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	☐ Prospectively registered
Registration date 07/06/2005	Overall study status Completed	☐ Protocol
Last Edited 28/03/2017	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ 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

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

Primary study design

Interventional

Study design

Randomised controlled trial

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

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