

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	<input type="checkbox"/> Prospectively registered
Registration date 07/06/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/03/2017	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled 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

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

26/11/2004

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

Age group

Adult

Sex

Both

Target number of participants

Not provided at time of registration

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)

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

European Commission

Alternative Name(s)

European Union, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκή Επιτροπή, Европейская комиссия, 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	01/08/2009		Yes	No