

Phase IV rectal artesunate clinical trial in the Kassena Nankana District of Ghana

Submission date 01/02/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 01/02/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/02/2009	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

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Additional identifiers

Study information

Scientific Title

Study objectives

The objective has been to establish whether, in patients with acute malaria who cannot take medication by mouth, rectal artesunate plus referral differs from rectal placebo plus referral in terms of death or permanent disability.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received on the 19th April 1999.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Malaria

Interventions

The sample size determination in the protocol specified that a total of 10,000 non per os patients would need to be randomised in order to detect a reduction of mortality from 5% to 3%.

Individual patients will be randomised to receive either AS suppository (intervention group) or placebo (comparator group). Patients in both groups will then be referred (and offered transport) immediately to the nearest hospital/health centre.

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Artesunate (AS)

Primary outcome(s)

1. Number of relevant deaths in the intervention and control arm assessed 7 - 30 days after enrolment (relevant defined as malaria positive patients in whom the death was probably /definitely preventable by the intervention)
2. Number of individuals with serious neurological disability in the intervention and control arms assessed at 7 - 30 days following enrolment in the study. Neurological disability defined as the development of new problems with feeding, walking, talking, sitting, sight, hearing, playing, balance and behaviour

Key secondary outcome(s)

1. Number of deaths in the intervention and control arm assessed 7 - 30 days following enrolment in the study
2. Number of cases of neurological disability in the intervention and control arms assessed at 7 - 30 days following enrolment in the study
3. Number of cases of neurological disability in malaria smear positive patients in the intervention and control arms assessed at 7 - 30 days following enrolment in the study

4. Number of cases of neurological disability in children in the intervention and control arms assessed at 7 - 30 days following enrolment in the study
5. Number of cases of neurological disability in pregnant women in the intervention and control arms assessed at 7 - 30 days following enrolment in the study
6. Number of deaths and neurological sequelae in the intervention and control arm in malaria smear positive patients who survived at least 8 hours but died before 7 days after enrolment in the study

Completion date

19/04/2001

Eligibility

Key inclusion criteria

1. Non per os children presenting to a peripheral health unit or traditional healer with clinically suspected *P. falciparum* malaria
2. Children from 6 months up to the age of 71 months old
3. Clinical diagnosis of probable *P. falciparum* malaria based on history from the parent/guardian and assessment of the Field Worker
4. Presence of one or more of the following conditions:
 - 4.1. Repeated vomiting (defined as more than three episodes immediately after feeding in the previous 24 hours)
 - 4.2. Inability to eat, drink or suck
 - 4.3. Recurrent convulsions (defined as at least two fits in the previous 24 hours)
 - 4.4. Altered consciousness (obtunded response to painful stimuli, coma, altered behaviour)
 - 4.5. So weak that cannot sit/stand/walk unaided and so cannot take oral medication
5. Consent by patient or parent/guardian (if patient younger than 18)
6. Community informed consent - at the start of the study in that area, community consent to the project would have been obtained

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 months

Upper age limit

71 months

Sex**Key exclusion criteria**

Ability to take an oral medication.

Date of first enrolment

19/04/1999

Date of final enrolment

19/04/2001

Locations

Countries of recruitment

Ghana

Switzerland

Study participating centre

20, Avenue Appia

Geneva-27

Switzerland

CH 1211

Sponsor information

Organisation

UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR)

ROR

<https://ror.org/01f80g185>

Funder(s)

Funder type

Research organisation

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)

Funder Name

European Commission (Belgium)

Alternative Name(s)

European Union, Comisi3n Europea, Europaische Kommission, EU-Kommissionen, Euroopa Komisjoni, EC, EU

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location**Funder Name**

WHO Global Malaria Programme

Funder Name

US Agency for International Development (USAID) (USA)

Funder Name

Irish Aid (Ireland)

Funder Name

Karolinska Institutet (Sweden)

Alternative Name(s)

Karolinska Institute, KI

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

Sweden

Funder Name

Sall Family Foundation (USA)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United States of America

Funder Name

University of Oxford Clinical Trial Service Unit (UK)

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	14/02/2009		Yes	No