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

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered		
01/02/2006		☐ Protocol		
Registration date 01/02/2006	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 23/02/2009	Condition category Infections and Infestations	[] 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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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

**Secondary identifying numbers** N/A

# 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

#### Secondary study design

Randomised controlled trial

#### Study setting(s)

Not specified

## Study type(s)

Treatment

#### Participant information sheet

# 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 measure

- 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

#### Secondary outcome measures

- 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

#### Overall study start date

19/04/1999

## Completion date

19/04/2001

# **Eligibility**

#### Key inclusion criteria

- 1. Non per os children presenting to a peripheral health unit or traditional healer with clinicallly 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

#### Age group

Child

#### Lower age limit

6 Months

#### Upper age limit

71 Months

#### Sex

**Not Specified** 

# Target number of participants

In this trial, it is not the number of patients recruited but the number of deaths that determine the statistical power of such a trial.

#### 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)

#### Sponsor details

20, Avenue Appia Geneva-27 Switzerland CH 1211

#### Sponsor type

Research organisation

#### Website

http://www.who.int/

#### **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, Comisión Europea, Europäische Kommission, EU-Kommissionen, Euroopa Komisjoni, Ευρωπαϊκής Επιτροπής, Εвροπεйската 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**

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**

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	14/02/2009		Yes	No