# Impact of early administration of artesunate suppository on childhood severe malaria in Tanzania

Submission date Recruitment status Prospectively registered 01/02/2006 No longer recruiting [ ] Protocol Statistical analysis plan Registration date Overall study status 01/02/2006 Completed [X] Results Individual participant data Last Edited Condition category Infections and Infestations 23/02/2009

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Melba Gomes

#### Contact details

20, Avenue Appia Geneva-27 Switzerland CH 1211 +41 (0)22 791 3813 gomesm@who.int

# Additional identifiers

Protocol serial number 980482

# 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 1st January 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 immediately to the nearest hospital/health centre.

## Intervention Type

Drug

#### Phase

**Not Specified** 

# 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

01/01/2001

# 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 (apparent age 6 months to 71 months) with suspected malaria who are too ill to take drugs by mouth
- 3. Individual informed consent consent must have been given (generally by thumb-print) by the patient or guardian of the sick person
- 4. 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

01/01/1999

# Date of final enrolment 01/01/2001

# Locations

#### Countries of recruitment

Switzerland

Tanzania

Study participating centre 20, Avenue Appia Geneva-27

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, Comisión Europea, Europäische 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