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

Submission date
01/02/2006

Registration date
01/02/2006

Last Edited
23/02/2009

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] 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

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, Европейската 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