ISRCTN78768405 https://doi.org/10.1186/ISRCTN78768405

Efficacy and safety of rectal artesunate in paediatric patients - a randomised controlled study (Ghana and Tanzania)

Submission date
05/04/2005

Recruitment status
No longer recruiting

Registration date
07/06/2005

Overall study status
Completed

Last Edited
15/08/2008

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Melba Gomes

Contact details
World Health Organization
20 Avenue Appia
Geneva-27
Switzerland
CH 1211
+41 (0)22 791 3813
gomesm@who.int

Additional identifiers

Protocol serial number
A20210 and A70334

Study information

Scientific Title

Study objectives
Hypothesis that clinical response rates in children aged 3 to 24 months with non per os malaria treated with rectal artesunate will not be inferior to those who receive standard treatment of parenteral Quinine.

Please note that as of 15/08/2008, this record was updated to include Tanzania in the countries of recruitment list. This country started recruitment on 08/05/2008 and was added in order to add to the patient numbers. Ethics approval for this site has also been added to this record, and the anticipated end date has also been updated. The previous anticipated end date for this trial was 30/09/2007.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved by:
1. The Committee on Human Research Publication and Ethics (CHRPE) of the School of Medical Sciences, Kwame Nkrumah University of Science and Technology, Kumasi on 20th January 2003
2. World Health Organization (WHO) Ethics Committee on 30th June 2003 and continuing review 15th November 2005 and 13 November 2007
3. The National Institute of Medical Research, Tanzania on 28th August 2007

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Malaria

Interventions
Group A: Artesunate 10 mg/kg, rectal
Group B: Quinine 20 mg dihydrochloride salt/kg, intra-muscular injection (followed by 10 mg/kg at 12 and 24 hours)

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Artesunate, quinine

Primary outcome(s)

28-day disease-free survival, defined as patients who survived the 28-day period of follow-up with the peripheral blood free of the original genotype of malaria parasites.

Key secondary outcome(s))
The parasitological outcomes and tolerability of a single dose of the rectal artesunate in children aged 3 to 24 months with non per os falciparum malaria.

Completion date
30/06/2010

Eligibility

Key inclusion criteria
1. Aged 3 to 24 months
2. Suspected malaria with no other obvious cause of illness
3. P. falciparum asexual parasitaemia greater than ++ (5 - 10 parasites/High Power Field [HPF])
4. Unable to eat, suck or drink, or repeatedly vomiting (more than three episodes over past 24 hours); or prostrate (unable to sit or stand if previously able to do so)
5. History of convulsions over the preceding 24 hours or impaired consciousness (Blantyre Coma Score less than five)
6. Parent/guardian informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 months

Upper age limit
24 months

Sex
All

Key exclusion criteria
1. Ability to tolerate oral intake
2. Acute diarrhoea defined as the presence of more than three episodes of watery stools in the preceding 24 hours
3. History of allergy to artemisinin compounds and/or quinine

Date of first enrolment
30/06/2003

Date of final enrolment
30/06/2010

Locations

Countries of recruitment
Ghana

Switzerland

Tanzania

Study participating centre
World Health Organization
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)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration