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Assessing delivery mechanism for the use of rectal artesunate in management of non per os malaria

Submission date	Recruitment status	[_] Prospectively registered
05/04/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/06/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/01/2021	Infections and Infestations	

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
A20679 - Tanzania; A20634 - Guinea-Bissau; A20130 - Uganda; A20133 - Ghana; A30173 - Zambia

Study information

Scientific Title
Assessing delivery mechanism for the use of rectal artesunate in management of non per os malaria

Study objectives
That a delivery system that uses caretakers (MOTHERS) to deliver rectal artesunate will significantly increase coverage of the drug compared with alternative deliery systems.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from:
1. National Ethics Committees in the participating countries
2. World Health Organization (WHO) Ethics Review Committee

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
Primary endpoint of coverage (% children requiring drug that got the drug) does not depend upon number of participants, therefore no exact number of participants. Community is the level of randomisation.

The three arms are:
1. Treatment using existing health care workers/volunteers/providers
2. Research informed community based system
3. Caretaker-mother based delivery system

Countries can choose to do a two arm study or a three arm study.

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
The coverage of non per os patients achieved.

Secondary outcome measures
1. The time taken to deliver the drug to the patient
2. The proportion of non per os patients who followed referral advice
3. The proportion of non per os patients who took consolidation treatment
4. The proportion of non per os patients who needed the drug but were excluded from treatment, and the proportion of per os patients who were given treatment and should have been excluded from treatment
5. The convenience and acceptability of treatment via the provider
6. The training requirements for the drug dispensers
7. The handling and utilisation of rectal artesunate suppositories, adherence to correct treatment procedures, adherence to training in recognition, referral to hospital/provision of consolidation treatment
8. Recording of treatment outcome
9. Recording severe adverse reactions
10. Documentation: number of suppositories used, number of suppositories in the village stock

Overall study start date
27/06/2003

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Children and adults of any age group
2. Clinical diagnosis of probable P. falciparum malaria
3. Consent by patient or parent guardian
4. Presence of one or more of the following conditions:
4.1. Repeated vomiting
4.2. Inability to eat, drink, or suck
4.3. Recurrent convulsions
4.4. Obtuned response to painful stimuli
4.5. Coma

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
N/A - see interventions section below

Key exclusion criteria
1. Children below three months age
2. Patients who are per os or can take drugs by mouth
3. Non-residents of the study area, unlikely to stay at least a week after treatment

Date of first enrolment
27/06/2003

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
Ghana

Guinea-Bissau

Switzerland

Tanzania

Uganda

Zambia

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)

Sponsor details
World Health Organization
20 Avenue Appia
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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)

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	15/12/2016	07/01/2021	Yes	No