

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

Submission date
05/04/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
07/06/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
07/01/2021

Condition category
Infections and Infestations

☐ 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

Protocol serial number

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 delivery 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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

The coverage of non per os patients achieved.

Key secondary outcome(s)

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

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. Obtunded response to painful stimuli
 - 4.5. Coma

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

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)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/12/2016	07/01/2021	Yes	No