

FIC - Training in malaria research in Uganda

Submission date 13/11/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 02/12/2005	Overall study status Completed	☐ Protocol
Last Edited 18/03/2008	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ 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

Study information

Scientific Title

Acronym
FIC

Study objectives

The proportion of convulsions terminated by buccal midazolam is higher than the proportion of convulsions terminated by rectal diazepam in children.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approved received from:

1. The Makerere University Medical School Research and Ethics Review Board (Uganda)
2. National Council of Science and Technology Institutional Review Board (IRB) (Uganda)
3. University of California San Francisco Institutional Review Board (IRB) (USA)

Primary study design

Interventional

Study design

Randomised double blind clinical trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Prolonged convulsions

Interventions

Rectal diazepam versus buccal placebo

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Midazolam, diazepam

Primary outcome(s)

Time taken to terminate convulsion within 10 minutes without re-occurrence of the convulsion in an hour.

Key secondary outcome(s)

1. Time taken to re-occurrence of convulsion after initial control
2. Time taken to terminate the convulsion within 10 minutes
3. Proportion of children who get respiratory depression within one hour after administration of the study drug

Completion date

20/05/2006

Eligibility

Key inclusion criteria

1. Age between 3 months to 12 years
2. Admission to Acute Care Unit during the study period
3. A child who presents to the Acute Care Unit with convulsions
4. Provision of informed consent to continue participation in the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

3 Months

Upper age limit

12 Years

Sex

All

Key exclusion criteria

1. Documented evidence of having recieved parenteral anticonvulsant in the past 24 hours
2. Cessation of convulsion before adminstration of study drug
3. Parent/caretaker verbally declines to participate in the study

Date of first enrolment

20/11/2005

Date of final enrolment

20/05/2006

Locations**Countries of recruitment**

Uganda

Study participating centre

Makerere Univeristy

Kampala

Uganda

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Sponsor information

Organisation

Fogarty International Center (FIC) (USA)

ROR

<https://ror.org/02xey9a22>

Funder(s)

Funder type

Government

Funder Name

Fogarty International Centre (FIC) (USA) (grant ref: TW007375)

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	01/01/2008		Yes	No