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FIC - Training in malaria research in Uganda

Submission date	Recruitment status	[_] Prospectively registered
13/11/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
02/12/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/03/2008	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

Protocol serial number
N/A

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)

Study design
Randomised double blind clinical trial

Primary study design
Interventional

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-occurence of the convulsion in an hour.

Key secondary outcome(s))
1. Time taken to re-occurence 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 adminstration 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