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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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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

### 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
Prolonged convulsions

### Interventions
Rectal diazepam versus buccal placebo

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Midazolam, diazepam

### Primary outcome measure
Time taken to terminate convulsion within 10 minutes without re-occurence of the convulsion in an hour.

### Secondary outcome measures
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

### Overall study start date
20/11/2005

### 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

### Age group
Child

### Lower age limit
3 Months

### Upper age limit
12 Years

### Sex
Both

### Target number of participants
350

### 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)

### Sponsor details
National Institutes of Health
Office of Communications
Building 31, Room B2C29
31 Center Drive
MSC 2220
Bethesda
United States of America
20892-2220
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ficinfo@nih.gov

### Sponsor type
Government

### Website
http://www.fic.nih.gov/

### ROR
https://ror.org/02xey9a22

# Funder(s)

**Funder type**
Government

**Funder Name**
Fogarty International Centre (FIC) (USA) (grant ref: TW007375)

# 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 | 01/01/2008 | | Yes | No |