ISRCTN13964268 https://doi.org/10.1186/ISRCTN13964268

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
-

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