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# A study of the concentration of ciprofloxacin in the body over time when given by mouth

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 03/06/2008 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 10/06/2008 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 02/02/2009 | Nutritional, Metabolic, Endocrine | [ ] Record updated in last year |

**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**
077092

## Study information

**Scientific Title**

Population pharmacokinetics of oral ciprofloxacin in children with severe malnutrition

## Study objectives
Mortality among children with severe malnutrition has remained high especially for those with proven bacteraemia. The currently recommended antibiotics offer sub-optimal cover for gram negative infections. Ciprofloxacin has good gram negative cover and can be given as an oral formulation owing to its good oral bioavailability over norfloxacin and good tissue penetration, which give concentrations that are at least equivalent to the minimum inhibitory concentration designated as the breakpoint of bacterial susceptibility in vitro.

It has been used widely in children with cystic fibrosis and immunocompromised children without any significant toxicity. The previous cost of the newer generations of oral quinolones was prohibitive and so pharmacokinetics (PK) in such populations could not be justified on the basis of limited application. The availability of cheaper formulations of the oral quinolones coupled with poor prognosis of children with severe malnutrition and gram negative infection on current standard treatment support the value of this study. No studies have been done on the PK of ciprofloxacin in children with severe malnutrition. This will provide a model to predict PK of ciprofloxacin in this group. Again this data will assist with the future national and international treatment guidelines for children with severe malnutrition.

Please note as of 02/02/2009 this record was amended to include a change to the interventions and a change to the number of participants. Ethics approval has been received for these amendments. Please also note that at this time a public title was added to this record and the initial public title moved to the scientific title field.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Ethics approval received from the Kenya Medical Research Institute (KEMRI) Ethical Review Committee (ERC) on the 27th March 2008 (Scientific Steering Committee [SSC] ref: 1331).

## Study design
Single centre, single arm, non-randomised, population PK trial

## Primary study design
Interventional

## Secondary study design
Non randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Severe acute malnutrition

## Interventions
Current information as of 02/02/2009:
In 36 children, ciprofloxacin will be given 2 hours after the child has received his/her first feed and medication. 16 children will have ciprofloxacin administered together with the first feed in order to investigate whether milk based formula diets (F75/F100) alters the pharmacokinetics of ciprofloxacin in children with severe malnutrition. Patients will be given ciprofloxacin orally, 10 mg/kg, twice daily for two days.

The children will be reviewed daily until they are disharged and then on day 28.

Initial information at time of registration:
Children will be divided into three groups based on severity. From each group there will be three subgroups for sampling times for four samples. Patients will be given ciprofloxacin orally, 10 mg /kg, twice daily for two days.

The children will be reviewed daily until they are disharged and then on day 28.

## Intervention Type
Drug

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
Ciprofloxacin

## Primary outcome measure
Determine the peak plasma concentrations of ciprofloxacin.

Measured:
Group 1: at 2, 4, 8, 24 hours
Group 2: at 3, 5, 9, 12 hours
Group 3: at 1, 3, 6, 10 hours

## Secondary outcome measures
Define which co-variates influence the pharmacokinetics of ciprofloxacin in this group of patients:
1. Age, assessed on admission (0 hour)
2. Sex, assessed on admission (0 hour)
3. Anthropometric indices, assessed on admission (0 hour)
4. Haemodynamic status, measured at 0 hour and 48 hour
5. Concomitant medications, reviewed every 4 hours

## Overall study start date
09/06/2008

## Completion date
26/03/2009

# Eligibility

### Key inclusion criteria
1. Aged over 6 months, either sex
2. Consent given
3. Severe malnutrition as defined by weight-for-height Z score (WHZ) less than -3 or bilateral oedema (of kwashiorkor) or mid-upper arm circumference (MUAC) less than 11.0 cm (if greater than 65 cm in length)
4. Able to take and retain oral treatment

### Participant type(s)
Patient

### Age group
Child

### Lower age limit
6 Months

### Sex
Both

### Target number of participants
36 (52 as of 02/02/2009)

### Key exclusion criteria
1. Admission plasma creatinine greater than 300 and evidence of intrinsic renal disease (hypertension or hyperkalaemia)
2. Coexisting bone or joint disease
3. Concurrent use of antacids, ketoconazole, theophylline, corticosteroids
4. Enrolment in another interventional study

### Date of first enrolment
09/06/2008

### Date of final enrolment
26/03/2009

# Locations

### Countries of recruitment
Kenya

### Study participating centre
**P.O. Box 230**
Kilifi
Kenya
80108

# Sponsor information

### Organisation
Kenya Medical Research Institute (KEMRI) Wellcome Trust Research Programme (Kenya)

### Sponsor details
P.O. Box 230
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80108

### Sponsor type
Research organisation

### Website
http://www.kemri-wellcome.org

### ROR
https://ror.org/04r1cxt79

# Funder(s)

### Funder type
Research organisation

### Funder Name
Kenya Medical Research Institute (KEMRI) Wellcome Trust Research Programme (Kenya) (ref: 077092)

# 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