ISRCTN31079753 https://doi.org/10.1186/ISRCTN31079753

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

Protocol serial number
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).

Primary study design
Interventional

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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed

No

Age group
Child

Lower age limit
6 Months

Sex
All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration