ISRCTN75784880 https://doi.org/10.1186/ISRCTN75784880

An open randomised comparison of Gatifloxacin versus Cefixime for the treatment of uncomplicated enteric fever

Submission date	Recruitment status	[_] Prospectively registered
22/07/2005	Stopped	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/07/2005	Stopped	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/03/2013	Infections and Infestations	[_] 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

061330

Study information

Scientific Title

Acronym
DM Study

Study objectives
To determine the relative efficacy of gatifloxacin and cefixime in treating culture confirmed enteric fever

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled 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
Enteric fever

Interventions
Open label randomised controlled trial of gatifloxacin versus cefixime.

Please note that due to safety reasons this trial was terminated on the 8th September 2005.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Gatifloxacin and cefixime

Primary outcome measure
Time to fever clearance

Secondary outcome measures
1. Development of complications
2. Blood culture sterilisation
3. Eradication of stool carriage
4. Need for retreatment
5. Development of enteric fever in household contacts
6. Treatment failure

Overall study start date
02/06/2005

Completion date
31/12/2006

Reason abandoned (if study stopped)
Safety reasons

Eligibility

Key inclusion criteria
1. The treating physician believes the diagnosis to be enteric fever
2. More than or equal to three days history of fever, headache and oral temperature more than or equal to 37.8 °C

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
169

Key exclusion criteria
1. Complicated typhoid (jaundice, shock, peritonism, gastrointestinal bleeding, myocarditis, encephalopathy)
2. Pregnancy
3. Lactation
4. Allergy to study drug

5. Quinolone, fluoroquinolone, macrolide or 3rd generation cephalosporin treatment within previous week
6. Unable to take oral medication

Date of first enrolment
02/06/2005

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Nepal

Viet Nam

Study participating centre
Oxford University Clinical Research Unit
Ho Chi Minh City
Viet Nam
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Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
University Offices
Wellington Square
Oxford
England
United Kingdom
OX1 2JD

Sponsor type
University/education

Website
http://www.ox.ac.uk

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 061330)

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:	27/06/2007		Yes	No