

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

Submission date 22/07/2005	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/07/2005	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 11/03/2013	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Jeremy Farrar

Contact details

Oxford University Clinical Research Unit
The Hospital for Tropical Diseases
190 Ben Ham Tu
Ho Chi Minh City
Viet Nam
5
+84 8 8362225
jfarrar@oucru.org

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

5

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