

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

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

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

Time to fever clearance

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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)

**ROR**  
<https://ror.org/052gg0110>

## Funder(s)

**Funder type**  
Charity

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

## Results and Publications

**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?
<a href="#">Results article</a>	Results:	27/06/2007		Yes	No