

# A research study to compare 2 antibacterial drugs, gatifloxacin with ciprofloxacin, for the treatment of dysentery in children

<b>Submission date</b> 15/01/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 18/01/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/03/2013	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

**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**  
061330

## Study information

**Scientific Title**

A randomised controlled trial of gatifloxacin versus ciprofloxacin for the treatment of bacillary dysentery in children

## Acronym

EG

## Study objectives

In 2004, The World Health Organization (WHO) organised a meeting of experts around the world and recommended that ciprofloxacin or other fluoroquinolones should be used to treat shigellosis in children as well as adults. However after being used for some years to treat shigellosis, the clinical response to ciprofloxacin treatment has decreased, strains of *Shigella dysenteriae* type 1 resistant to ciprofloxacin were also detected. This is why searching for alternative regimens is obviously needed. This study will compare the currently recommended WHO regimen with a newer, affordable and potentially more active fluoroquinolone, i.e., gatifloxacin.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from Oxford Tropical Research Ethics Committee on the 20th June 2006 (ref: OXTREC 010-06).

## Study design

Open-label randomised controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

*Shigella* dysentery

## Interventions

Patients are randomised to:

1. Ciprofloxacin 15 mg/kg body weight taken orally every 12 hours for a total of 6 doses in 3 days, or
2. Gatifloxacin 10 mg/kg body weight taken orally every 24 hours for a total of 3 doses in 3 days

Follow-up will occur for 7 - 10 days after discharge from the hospital.

## Intervention Type

Drug

## Phase

Not Specified

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

Ciprofloxacin, gatifloxacin

### **Primary outcome(s)**

Failure of treatment:

1. Persistent fever at Day 5
2. Failure to clear completely the admission symptoms at Day 5
3. Stool culture positive at Day 3 of treatment
4. Need for rescue treatment with ceftriaxone
5. The development on treatment of any complication

### **Key secondary outcome(s)**

1. Fever clearance time: from the start of treatment until axillary temperature falls to 37.5°C and remains at or below this value for greater than 48 hours
2. Bloody diarrhoea clearance time: the time to the last stool containing visible blood passed
3. Diarrhoea clearance time: the time to the first formed stool
4. Bacterial clearance time: time to the last positive stools culture for Shigella

### **Completion date**

30/03/2009

## **Eligibility**

### **Key inclusion criteria**

1. Patients aged 0 - 14, either sex
2. Symptomatic uncomplicated dysentery
3. Gives consent

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Child

### **Lower age limit**

0 years

### **Upper age limit**

14 years

### **Sex**

All

### **Key exclusion criteria**

No consent given.

### **Date of first enrolment**

01/06/2006

**Date of final enrolment**

30/03/2009

## Locations

**Countries of recruitment**

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)

**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**

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Results article</a>	results	15/12/2009		Yes	No
<a href="#">Results article</a>	results	01/08/2011		Yes	No