

An open randomised study to assess the efficacy of gatifloxacin versus azithromycin for the treatment of uncomplicated typhoid fever

Submission date 22/07/2005	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 22/07/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 11/03/2013	Condition category Infections and Infestations	☐ 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

Acronym

BJ Study

Study objectives

There has been a dramatic change in Viet Nam in the sensitivity of *Salmonella typhi* (the bacteria that causes typhoid fever) to all antibiotics. In the Mekong Delta more than 95% of isolates are resistant to all first line antibiotics (defined as multidrug resistant) and show significantly poorer clinical response to the older fluoroquinolones. There is the very real risk that typhoid fever in Viet Nam will soon become effectively untreatable. There is an urgent need to develop treatments that combine speed of clinical response, reduction in secondary transmission and protection from the development of resistance. From uncontrolled clinical data from a small number of patients treated at Dong Thap Hospital in Viet Nam and from in vitro sensitivity data gatifloxacin maybe a suitable new treatment for multidrug resistant Typhoid Fever.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Typhoid fever

Interventions

An open randomised two-way comparison of gatifloxacin (10 mg/kg/day) versus azithromycin (20 mg/kg/day) for seven days for the treatment of symptomatic uncomplicated typhoid fever.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Gatifloxacin and azithromycin

Primary outcome(s)

Fever Clearance Time.

Key secondary outcome(s)

Clinical and Microbiological Failure.

Completion date

30/09/2006

Eligibility

Key inclusion criteria

Patients will be eligible if they have suspected or culture proven enteric fever provided:

1. They give fully informed consent
2. They are not obtunded not jaundiced
3. There are no signs of gastrointestinal (GI) bleeding or any other evidence of severity (see below)
4. No history of hypersensitivity to either of the trial drugs
5. No treatment with a quinolone or 3rd generation cephalosporin or macrolide within one week of hospital admission
6. They are not pregnant

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. Pregnancy or lactation
2. Any signs of symptoms of severe disease
3. No informed consent

Date of first enrolment

01/10/2005

Date of final enrolment

30/09/2006

Locations

Countries of recruitment

Viet Nam

Study participating centre

Hospital for Tropical Diseases
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

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	21/05/2008		Yes	No