

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/07/2005	Overall study status Completed	<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

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

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

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

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 measure

Fever Clearance Time.

Secondary outcome measures

Clinical and Microbiological Failure.

Overall study start date

01/10/2005

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

Age group

Not Specified

Sex

Not Specified

Target number of participants

To be added

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)

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	21/05/2008		Yes	No