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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 22/07/2005	**Overall study status** Completed	
Last Edited 11/03/2013	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Jeremy Farrar

Contact details
Hospital for Tropical Diseases
The Hospital for Tropical Diseases
Oxford University Clinical Research
190 Ben Ham Tu
Ho Chi Minh City
Viet Nam
5
+84 88362225
jfarrar@oucru.org

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