

An open randomised study to assess the efficacy of gatifloxacin versus chloramphenicol for the treatment of uncomplicated typhoid fever in Kathmandu, Nepal

Submission date 11/04/2006	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 11/04/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 20/03/2013	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; OXTREC 002-06

Study information

Scientific Title

Acronym

ED

Study objectives

There has been a steady change in Kathmandu in the sensitivity of *Salmonella typhi* (the bacteria that causes typhoid fever) to all antibiotics. In Kathmandu in 2005 less than 5% of isolates are resistant to first line antibiotics including Chloramphenicol but they do show significantly poorer clinical response to the older fluoroquinolones (Ciprofloxacin and Ofloxacin) with high rates of Nalidixic acid resistance. There has been interest in Kathmandu and in the Indian Sub-Continent about returning to the use of the classical antibiotics for typhoid including Chloramphenicol. It is unclear in this environment, whether this is a reliable therapy for enteric fever or whether Gatifloxacin, a new generation and affordable fluoroquinolone, would be the better choice.

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

Typhoid fever

Interventions

Gatifloxacin versus Chloramphenicol.

Added as of 20/09/2007:

This trial was stopped temporarily in September 2006 at the request of the Nepal Health Research Council and Department of Drug Administration after the reports of dysglycaemia associated with gatifloxacin.

The trial was resumed on Dec 2006 after the ethical committee and the Drug Administration authority were assured that dysglycaemia was not a problem in the young population who are most affected by enteric fever and all the patients in the trial were monitored closely for any dysglycaemia by fingerprick glucose testing.

Please note that due to the reasons stated above, the anticipated end date of this trial has changed. The previous end date of this trial was 30th April 2007.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Gatifloxacin, Chloramphenicol

Primary outcome(s)

Failure of treatment defined as the occurrence of any one of the following:

1. Persistent fever at day ten of treatment
2. Failure to clear completely the admission symptoms at day ten
3. Blood culture positive at day ten of treatment
4. Need for 'rescue' treatment with ceftriaxone
5. Culture confirmed relapse within 28 days of starting therapy
6. The development on treatment of any complication:
 - 6.1 Clinically significant bleeding
 - 6.2. Fall in the Glasgow Coma Score
 - 6.3. Perforation of the gastrointestinal tract
 - 6.4. Admission to hospital within 28 days of starting therapy

Key secondary outcome(s))

No secondary outcome measures

Completion date

30/06/2008

Reason abandoned (if study stopped)

This trial was stopped in September 2006 but has since restarted again (see interventions for more details of this - 20/09/07). In the light of the reports on dysglycaemia in elderly patients in North American the Dept of Drug Administration (DDA) in Nepal have asked us to provide some additional information on Gatifloxacin. Whilst providing this additional information and following discussion with the DDA and the Nepal Health Research Council, we have suspended the study. As the investigators, we have had no cause for concern during the study and have not identified any problems with glycaemic control on history taking, regular blood glucose monitoring and during the follow up of the study. We are in the process of providing the additional information requested and will let you know of the decision of the DDA as soon as we know of it. We hope that we will be able to restart the study following their recommendation. At the time of suspension we have recruited 404 patients, 180 with confirmed enteric fever. As a randomised study we do not feel that the suspension has an impact on the study conduct whilst we wait for the decision.

Eligibility**Key inclusion criteria**

Any patient with suspected uncomplicated enteric fever who gives consent.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. No consent
2. Pregnancy

Date of first enrolment

01/05/2006

Date of final enrolment

30/06/2008

Locations**Countries of recruitment**

Nepal

Study participating centre

Patan Hospital

Kathmandu

Nepal

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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	01/06/2011		Yes	No