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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

Registration date
11/04/2006

Overall study status
Completed

Last Edited
20/03/2013

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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; 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 floroquinolone, 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

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
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 measure
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

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/05/2006

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

Age group
Adult

Sex
Both

Target number of participants
320

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)

Sponsor details
University Offices
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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	01/06/2011		Yes	No