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A comparison of azithromycin and ofloxacin in the treatment of typhoid in adult patients in Laos

Submission date
07/12/2005

Recruitment status
Stopped

Registration date
07/12/2005

Overall study status
Stopped

Last Edited
02/02/2009

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Paul Newton

Contact details
Microbiology laboratory
Ministry of Health
Mahosot Hospital
Mahosot Road
Vientiane
Lao People's Democratic Republic
-
+856 (0)21 250752
paul@tropmedres.ac

Additional identifiers

Protocol serial number
066828

Study information

Scientific Title
A randomised clinical trial of Azithromycin versus Ofloxacin in the treatment of adults with uncomplicated typhoid fever at Mahosot Hospital, Vientiane, Lao People's Democratic Republic (PDR)

Acronym
AO

Study objectives
To conduct an open, randomised comparative clinical trial of oral azithromycin, versus ofloxacin in the treatment of 88 adults with uncomplicated typhoid fever at Mahosot Hospital, Vientiane, Lao PDR. The primary outcome measures will be fever clearance, cure rate, relapse rate and S. typhi stool carriage rate.

Trial details submitted to the Wellcome Trust 8th June 2005.

Please note that as of 21/01/08 this trial was stopped. This is because the incidence of typhoid in Vientiane has declined. We have permission to continue the trial should the incidence rise or if there is an epidemic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Oxford Tropical Ethics Committee (OXTREC) gave approval on the 6th May 2004 (ref: OXTREC 006-04)
2. Faculty of Medical Sciences, Vientiane, Laos Ethical Committee gave approval on the 2nd April 2004 (ref: FMS 2/4/2004)

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Typhoid fever

Interventions
A randomised, open clinical trial with random allocation to three days ofloxacin or three days azithromycin.

Please note that the anticipated end date has been extended to 31st December 2008.

Intervention Type
Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)
Azithromycin and ofloxacin

Primary outcome(s)
The primary outcome measures are fever clearance, cure rate, relapse rate and S. typhi stool carriage rate.

Key secondary outcome(s)
No secondary outcome measures

Completion date
31/12/2006

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. Adult (more than or equal to 15 years, either sex) non-pregnant patients with suspected or blood culture proven typhoid
2. Fever more than 37.5 °C
3. Informed written consent to the study
4. Able to stay in hospital for seven days
5. Able to take oral medication
6. Body weight more than 40 kg
7. Likely to be able to complete six months follow up
8. None of the exclusion criteria

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Known hypersensitivity to ofloxacin or azithromycin
2. Administration of chloramphenicol, co-trimoxazole, ampicillin, azithromycin or a fluoroquinolone during the previous week
3. Pregnancy or breast feeding
4. Contraindications to ofloxacin or azithromycin
5. Evidence for severe typhoid

Date of first enrolment
01/05/2004

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Lao People's Democratic Republic

Study participating centre
Microbiology laboratory
Vientiane
Lao People's Democratic Republic
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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: 066828)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration