

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

Submission date 07/12/2005	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered
Registration date 07/12/2005	Overall study status Stopped	<input type="checkbox"/> Protocol
Last Edited 02/02/2009	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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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