

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

<b>Submission date</b> 07/12/2005	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 07/12/2005	<b>Overall study status</b> Stopped	<input type="checkbox"/> Protocol
<b>Last Edited</b> 02/02/2009	<b>Condition category</b> 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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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

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)

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

**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 measure**

The primary outcome measures are fever clearance, cure rate, relapse rate and *S. typhi* stool carriage rate.

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

01/05/2004

**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

**Age group**

Adult

**Sex**

Both

**Target number of participants**

88

**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)

**Sponsor details**

Churchill Hospital

CCVTM

Headington

Oxford

England

United Kingdom  
OX3 7LJ

**Sponsor type**  
University/education

**Website**  
[http://www.jr2.ox.ac.uk/ndm/Tropical\\_Medicine](http://www.jr2.ox.ac.uk/ndm/Tropical_Medicine)

**ROR**  
<https://ror.org/052gg0110>

## **Funder(s)**

**Funder type**  
Charity

**Funder Name**  
The Wellcome Trust (UK) (grant ref: 066828)

## **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