# Oral doxycycline versus oral azithromycin in the treatment of Scrub and Murine Typhus in Laos

Submission date	<b>Recruitment status</b> No longer recruiting	Prospectively registered	
07/12/2005		☐ Protocol	
Registration date 07/12/2005	Overall study status Completed	Statistical analysis plan	
		[X] Results	
Last Edited	Condition category	Individual participant data	
23/09/2020	Infections and Infestations		

## 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, 106698/Z/14/Z

# Study information

Scientific Title

An open, randomised clinical trial of three days oral doxycycline versus seven days oral doxycycline versus three days oral azithromycin in the treatment of Scrub and Murine Typhus

#### Acronym

**MUT and SUT** 

## **Study objectives**

That fever clearance times and the frequencies of relapse and treatment failure do not differ between three days oral doxycycline versus seven days oral doxycycline versus three days oral azithromycin in the treatment of scrub and murine typhus.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

- 1. Oxford Tropical Ethics Committee (OXTREC), 27/03/2003, ref: OXTREC 003-03
- 2. Faculty of Medical Sciences, Vientiane, Laos Ethical Committee, 03/06/2003, ref: FMS 3-6-2003

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Scrub typhus, murine typhus

#### Interventions

An open, randomised comparative trial of three days oral doxycycline versus seven days oral doxycycline versus three days oral azithromycin.

## Added 02/02/2009:

Each of the two diseases have the same three treatment arms:

- 1. Oral doxycycline 100 mg every 12 hours for 7 days (after a 200 mg loading dose)
- 2. Doxycycline 100 mg every 12 hours for 3 days (after a 200 mg loading dose)
- 3. Oral azithromycin 500 mg on day 1 and then 250 mg every 24 hours for 2 more days

Follow up is for one year.

## Intervention Type

Drug

#### Phase

Not Applicable

## Drug/device/biological/vaccine name(s)

Doxycycline, azithromycin

## Primary outcome(s)

Current information as of 02/02/2009:

Fever clearance time and area under the fever-time curve during inpatient stay.

Initial information at time of registration:

- 1. Fever clearance times
- 2. Frequencies of treatment failure
- 3. Frequencies of relapse

## Key secondary outcome(s))

Added as of 02/02/2009:

- 1. Treatment failure frequency
- 2. Relapse frequency

## Completion date

31/12/2009

# Eligibility

## Key inclusion criteria

Current information as of 02/02/2009:

- 1. Adult (greater than 15 years) non-pregnant patients with suspected typhus. Suspected typhus will be defined as undifferentiated fever (aural temperature greater than 37.5°C), with or without an eschar, with a positive scrub typhus Lateral Flow IgM result or a murine typhus IgM Dip-S-Ticks result
- 2. Written informed consent to the study
- 3. Able to stay in hospital for the duration of the treatment (up to 7 days) and high likelihood of completing at least 4 weeks follow up
- 4. Able to take oral medication
- 5. A negative urinary pregnancy test for all women of child bearing age
- 6. None of the exclusion criteria

Initial information at time of registration:

- 1. Adult (more than or equal to 15 years, either sex) non-pregnant patients with suspected typhus, with a positive scrub typhus Lateral Flow result or a murine typhus Dip-S-Ticks result
- 2. Written informed consent
- 3. Able to stay in hospital for the duration of the treatment
- 4. High likelihood of completing at least four weeks follow up
- 5. Able to take oral medication
- 6. A negative urinary pregnancy test for all women of childbearing age
- 7. None of the exclusion criteria

## Participant type(s)

**Patient** 

## Healthy volunteers allowed

No

## Age group

Adult

#### Sex

ΔII

#### Key exclusion criteria

Current information as of 02/02/2009:

- 1. Known hypersensitivity to tetracycline, doxycycline or azithromycin
- 2. Administration of chloramphenicol, doxycycline, tetracycline, fluoroquinolones or azithromycin during the preceeding week
- 3. Pregnancy or breastfeeding
- 4. Contraindications to doxycycline: severe hepatic impairment, known systemic lupus erythematosus (SLE)
- 5. Contraindications to azithromycin: severe hepatic impairment
- 6. Severe typhus defined as:
- 6.1. Reduced level of consciousness
- 6.2. Clinical jaundice
- 6.3. Shock (blood pressure [BP] systolic less than 80 mmHg)
- 6.4. Vomiting sufficient to disallow the use of oral medication
- 6.5. Clinical or radiological evidence for lung involvement
- 6.6. Clinical evidence for meningitis/encephalitis or the need for a lumbar puncture (LP)
- 6.7. Any other syndrome which in the opinion of the admitting doctor constitutes severe typhus (reason must be stated)

#### Initial information at time of registration:

- 1. Known hypersensitivity to tetracycline, doxycycline or azithromycin
- 2. Administration of chloramphenicol, doxycycline, tetracycline, fluoroquinolones or azithromycin during the preceeding week
- 3. Pregnancy or breast feeding
- 4. Contraindications to doxycycline or azithromycin and severe typhus

#### Date of first enrolment

04/08/2003

#### Date of final enrolment

31/12/2009

## Locations

#### Countries of recruitment

Lao People's Democratic Republic

## Study participating centre Mahosot Hospital

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**

Wellcome Trust (grant ref: 066828)

## Alternative Name(s)

## **Funding Body Type**

Private sector organisation

## **Funding Body Subtype**

International organizations

#### Location

**United Kingdom** 

## **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	15/02/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/202	.5 No	Yes