

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

Submission date 07/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 07/12/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 23/09/2020	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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

All

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