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

Submission date	Recruitment status 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

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Contact details

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Additional identifiers

EudraCT/CTIS number

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IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

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 measure

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

Secondary outcome measures

Added as of 02/02/2009:

- 1. Treatment failure frequency
- 2. Relapse frequency

Overall study start date

04/08/2003

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

Age group

Adult

Sex

Both

Target number of participants

71 patients in each arm for each disease (total: 213 for each disease) (added 02/02/2009)

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

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

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/02/2019		Yes	No