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

Submission date	Recruitment status	[_] Prospectively registered
07/12/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/12/2005	Completed	[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

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Additional identifiers

EudraCT/CTIS number

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
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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

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