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# Melioidosis ERadication THerapy/THailand

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 23/11/2005 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 23/11/2005 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 19/06/2015 | 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

**Protocol serial number**
077166

## Study information

**Scientific Title**
A comparison of doxycycline plus trimethoprim-sulphamethoxazole versus trimethoprim-sulphamethoxazole as maintenance therapy for melioidosis

## Acronym
MERTH

## Study objectives
To evaluate the efficacy, effectiveness and compliance of Trimethoprim-Sulphamethoxazole (TMP-SMX) compared with doxycycline, Trimethoprim (TMP), and Sulphamethoxazole (SMX) in the oral maintenance phase treatment of melioidosis.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
1. The Ethical Review Committee for Research in Human Subjects, Ministry of Public Health, Thailand (IRB00001629), 27/07/2005, ref: 67/2548
2. The Khon Kaen University Ethics Committee (IRB00001189), 20/05/2005, ref: HE7471005
3. The Oxford Tropical Research Ethics Committee (OXTREC), 04/11/2005, ref: 021-05

## Study design
Placebo-controlled randomised multicentre study

## Primary study design
Interventional

## Study type(s)
Treatment

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

## Interventions
The patients will be randomised into two groups, and the randomisation will be performed in advance by blocks of ten. Pre-prepared treatment-containing packs will be labelled with the consecutive study numbers. The study drugs include either of the combinations below:

1. Three drugs:
a. Co-trimoxazole (10 mg TMP and 50 mg SMX/kg/day): three adult tablets (80 mg TMP/tab), twice daily. The dose of co-trimoxazole will be reduced to two tablets, twice daily in case of patients with creatinine clearance less than 30 ml/min or who weigh less than 35 kg, and increased to four tablets, twice daily in case of patients who weigh more than 65 kg.
b. Doxycycline (4 mg/kg/day): one tablet twice daily.

2. Two drugs:
a. Co-trimoxazole (10 mg TMP and 50 mg SMX/kg/day): three adult tablets (80 mg TMP/tab), twice daily. The dose of co-trimoxazole will be reduced to two tablets, twice daily in case of patients with creatinine clearance less than 30 ml/min or who weigh less than 35 kg, and increased to four tablets, twice daily in case of patients who weigh more than 65 kg.
b. Placebo (identical tablet as doxycycline): one tablet twice daily.

## Intervention Type
Drug

### Phase
Not Applicable

### Drug/device/biological/vaccine name(s)
Co-trimoxazole (Trimethoprim and sulphamethoxazole), doxycycline

### Primary outcome(s)
1. Mortality
2. Recurrent disease: this is defined as clinical features of melioidosis after initial improvement, in association with cultures from any site positive for Burkholderia pseudomallei. This can be any time point during or after stopping antibiotic treatment.

### Key secondary outcome(s))
1. Clinical recurrence: recurrent clinical features of melioidosis treated as such but not confirmed by positive culture
2. Treatment failure: clinical decision to change treatment according to inadequate response to therapy
3. Adverse drug reactions, including drug allergy
4. Drug compliance: based on interview and pill counting

### Completion date
31/10/2009

## Eligibility

### Key inclusion criteria
1. Culture-confirmed melioidosis
2. Satisfactory completion of intravenous therapy and able to take oral medication
3. Patients with mild localised disease who are not considered to require intravenous treatment by their primary physician are eligible if they agree to return for follow up
5. Aged over 14 years, either sex
6. High likelihood of completing at least six months follow up
7. Willingness to participate in the study and written, informed consent obtained from the patient

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Sex
All

### Key exclusion criteria
1. Pregnancy or breast feeding
2. Contraindications to doxycycline: severe hepatic impairment (aspartate aminotransferase

[AST], alanine aminotransferase [ALT] more than or equal to five times of upper limit of normal)
3. Contraindications to TMP-SMX: Glucose-6-phosphate dehydrogenase (G6PD) deficiency, renal impairment (creatinine clearance less than 15 ml/min)
4. History of hypersensitivity to doxycycline, TMP or SMX
5. Infecting isolate is resistant to TMP-SMX by E-test
6. Relapse melioidosis with disease free interval of less than two years

### Date of first enrolment
26/10/2005

### Date of final enrolment
31/10/2008

## Locations

### Countries of recruitment
Thailand

### Study participating centre
**Khon Kaen University**
Khon Kaen
Thailand
40002

## Sponsor information

### Organisation
Khon Kaen University (Thailand)

### ROR
https://ror.org/03cq4gr50

## Funder(s)

### Funder type
Charity

### Funder Name
Wellcome Trust (UK) (grant ref: 077166)

### 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 | 01/03/2014 | | Yes | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |