

# Melioidosis ERadication THerapy/THailand

<b>Submission date</b> 23/11/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/11/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 19/06/2015	<b>Condition category</b> 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

**Contact name**  
Dr Ploenchan Chetchotsakd

**Contact details**  
Khon Kaen University  
Department of Medicine  
Faculty of Medicine  
Srinagarind Hospital  
Mitrapharp Highways  
Khon Kaen  
Thailand  
40002  
+66 (0)4 3363168  
ploencha@kku.ac.th

## 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?
<a href="#">Results article</a>	results	01/03/2014		Yes	No