

Melioidosis ERadication THerapy/THailand

Submission date 23/11/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 23/11/2005	Overall study status Completed	☐ Protocol
Last Edited 19/06/2015	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ Results
		☐ 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

Primary study design

Interventional

Study design

Placebo-controlled randomised multicentre study

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