ISRCTN86140460 https://doi.org/10.1186/ISRCTN86140460

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

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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 below to request a patient information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
26/10/2005

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

Age group
Mixed

Sex
Both

Target number of participants
600

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)

Sponsor details
Department of Medicine
Faculty of Medicine
Srinagarind Hospital
Mitrapharp Highways
Khon Kaen
Thailand
40002

Sponsor type
University/education

Website
http://www.kku.ac.th/eng/index.html

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

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	01/03/2014		Yes	No