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Effect of malaria prevention on in-hospital mortality among severely ill tuberculosis patients

Submission date	Recruitment status	[ ] Prospectively registered
05/09/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/09/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
27/09/2010	Infections and Infestations	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Raffaella Colombatti

Contact details
Via Giustiniani 2
Padova
Italy
35100
+39 345 535 6570
rcolombatti@gmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of malaria prevention on in-hospital mortality among severely ill tuberculosis patients: a single centre non-randomised trial

Acronym
TBMPrev

Study objectives
To reduce mortality in admitted tuberculosis (TB) patients during the rainy season through a three-step malaria prevention program.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethics Committee (Ethics Committee of Hospital Raoul Follereau) approved in December 2004.

Study design
Single centre non-randomised trial

Primary study design
Interventional

Secondary study design
Non randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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
Malaria/tuberculosis

Interventions
1. A permethrin-treated bednet will be given to every patient upon admission since 2005 and during all the three years of the intervention; bednets will be retreated every 30 - 45 days.
2. Environmental disinfection will be performed monthly with permethrin-based products by appropriately trained hospital staff according to manufactor's instructions during the rainy season of 2006 and 2007; spraying will be conducted both outdoor (with Microsin) and indoor

(with Petrin L) on doors and window frames.
3. Prophylaxis with once daily trimethoprim 80 mg/sulfamethoxazole 400 mg tablet will be given to every patient admitted from July 1st to October 30th only in 2007

Treatment will be given for free to all patients and health education classes on malaria prevention have been given since 2005.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Death or discharge from hospital

Secondary outcome measures
1. Drop-outs (defined as voluntary discharge from hospital before recovery against physicians advice and/or treatment abandonment)
2. Percentage of attendance of health education classes

Overall study start date
01/01/2005

Completion date
31/12/2007

Eligibility

Key inclusion criteria
All patients (aged 0 - 75 years, either sex) admitted to the National Reference Hospital for Tuberculosis and Lung Diseases, Hospital "Raoul Follereau"

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
900 - 1000

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
01/01/2005

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
Guinea-Bissau

Italy

Study participating centre
Via Giustiniani 2
Padova
Italy
35100

Sponsor information

Organisation
Aid, Health and Development (AHEAD) - Onlus (Italy)

Sponsor details
c/o Fabio Riccardi
Via San Damaso 15
Rome
Italy
00165

Sponsor type
Research organisation

Website
http://www.ahead-onlus.org

ROR
https://ror.org/00d0m6v41

Funder(s)

Funder type
Charity

Funder Name
The Global Fund to Fight AIDS, Tuberculosis and Malaria (Switzerland)

Funder Name
US Agency for International Development (USAID) (USA)

Funder Name
Aid, Health and Development (AHEAD) - Onlus (Italy)

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