

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

Submission date 05/09/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/09/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/09/2010	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

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

Study type(s)

Prevention

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 manufacturer'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(s)

Death or discharge from hospital

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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)

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**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration