

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

Submission date
05/09/2010

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
27/09/2010

Overall study status
Completed

☐ Statistical analysis plan

☐ Results

Last Edited
27/09/2010

Condition category
Infections and Infestations

☐ Individual participant data

☐ 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

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 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 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