

# A randomised placebo controlled double blind clinical trial of vitamin D in the treatment of tuberculosis

<b>Submission date</b> 13/04/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 21/05/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/02/2009	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

## Study information

**Scientific Title**

**Acronym**  
TBD

**Study objectives**

Vitamin D plays an important role in the immune system, and may help the host in combatting active infection with Mycobacterium Tuberculosis.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Not provided at time of registration

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Tuberculosis

**Interventions**

100,000 IU cholecalciferol or placebo in drinkable ampoule at diagnosis, 5 months and 8 months clinical follow up (i.e. total 300,000 IU).

**Intervention Type**

Supplement

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Vitamin D

**Primary outcome(s)**

Clinical status (time to cure by sputum clearance, weight gain, clinical score) after treatment

**Key secondary outcome(s)**

Mortality

**Completion date**

31/12/2005

**Eligibility****Key inclusion criteria**

Adult patients diagnosed with tuberculosis (smear positive and smear negative) living in the field site study area

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

None. Withdrawal if signs of hypercalcaemia or allergy to vitamin D.

**Date of first enrolment**

01/11/2003

**Date of final enrolment**

31/12/2005

**Locations****Countries of recruitment**

Guinea-Bissau

**Study participating centre****Bandim Health Project**

Bissau Codex

Guinea-Bissau

1004

**Sponsor information****Organisation**

Bandim Health Project (Guinea-Bissau)

**ROR**

<https://ror.org/002nf6q61>

**Funder(s)****Funder type**

Industry

**Funder Name**

Danish Research Council for Development Research (Denmark) (ref: 91163) - project expenses

**Funder Name**

University of Aarhus (Denmark) - salary of lead principal investigator

**Funder Name**

Crinex Pharmaceuticals (France) - free cholecalciferol and placebo

## 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?
<a href="#">Results article</a>	results	01/05/2009		Yes	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes