

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

Submission date
13/04/2004

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
21/05/2004

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
11/02/2009

Condition category
Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

N/A

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?
Results article	results	01/05/2009		Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes