

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

Study website

http://www.indepth-network.org/dss_site_profiles/bandim.pdf

Contact information

Type(s)

Scientific

Contact name

Dr Christian Wejse

Contact details

Bandim Health Project

Apartado 861

Bissau Codex

Guinea-Bissau

1004

+245 255543

wejse@hotmail.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

Mortality

Overall study start date

01/11/2003

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

Age group

Adult

Sex

Both

Target number of participants

500

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)

Sponsor details

Apartado 861
Bissau Codex
Guinea-Bissau
1004
+245 201489
psb@mail.gtelecom.gw

Sponsor type

Not defined

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2009		Yes	No