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

Submission date	Recruitment status	[_] Prospectively registered
13/04/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/05/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/02/2009	Infections and Infestations	

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

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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
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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