Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Efficacy of high dose cholecalciferol on smear positive pulmonary tuberculosis treatment

Protocol summary

Summary

(1) The study is aimed to assess the effect of high dose vitamin D on treatment of pulmonary tuberculosis (with a hypothesis that high dose vitamin D speeds up the recovery) (2) Study Design: A double blind parallel randomized clinical trial lasting about one year or until total cases and controls are 100 patients (3) Study: Patients referred to pulmonary disease clinic of Bandar Abbas Health care center who meet the inclusion criteria, select a blue or red colored paper to be allocated in case or control group. According to the color of the paper the physician, gives the patient a package containing standard antituberculous regimen with vitamin D or placebo according to the color of the paper unaware of the contents. Prior to initiation of the treatment, a base line CBC, LFT, BUN, Cr, HIV Elisa, PTH, sputum smear and CXR are taken. Sputum smear is repeated on 2nd, 3rd, 4th, 5th and 6 month of therapy. Finally in the 6th month of treatment a CXR is taken. The patients are advised to refrain from taking Mg containing anti-acids (4) The participants meeting the inclusion criteria (1)Age 18-65 yrs 2)Inclining to participate in the study 3)Smear positive pulmonary tuberculosis 4)Anti-tuberculous regimen has not started 5)Not consuming vitamin D complements) are included in the study and are excluded from the study if meet any of the following criteria (1) Positive history of anti-tuberculous treatment 2)Extrapulmonary tuberculosis 3)Immunosuppression, HIV / AIDS, renal insufficiency, hepatic insufficiency, diabetes, organ transplant, sarcoidosis, hyperparathyroidism 4)Treatment with thiazides or corticosteroids 5)Lactation or pregnancy 6) Symptomatic cardiac disease7)Allergy to anti tuberculous medications or intolerance to complete the treatment 7)Concomitant use of drugs interacting with serum Vitamin D levels such as Phenytoin, Phenobarbital, Carbamazepin, Theophylline8) death) (5) Intervention: Vitamin D 50000 IU/day from DANA pharmaceutics and the placebo is also produced by DANA pharmaceutics. The red paper is for the intervention group and the blue paper is for the placebo group (6) Outcome: main outcome is considered sputum and chest x ray clearance as indicators of cure

General information

Acronym

HDC-PTB

IRCT registration information

IRCT registration number: **IRCT2013061610326N1**
Registration date: **2013-08-26, 1392/06/04**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-08-26, 1392/06/04

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Hormozgan University of Medical Sciences, Department of Resaerch and Technology

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy of high dose cholecalciferol on smear positive pulmonary tuberculosis treatment

Public title
Efficacy of high dose vitamin d on smear positive pulmonary tuberculosis treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 1- age of 18-65 years 2- inclined to participate in the study 3- smear positive pulmonary tb 4- has not started antituberculous treatment 5- does not use vitamin d supplement Exclusion criteria: 1- use of antituberculous treatment regimen 2-extrapulmonary or smear negative tb 3-immunosuppresion, HIV/AIDS, renal insufficiency, hepatic failure, diabetes, organ transplant, sarcoidosis, hyperparathyroidism 5- treatment with corticosteroids, thiazides 6-symptomatic cardiac disease 7- allergy to antituberculous medications or intolerance to complete the treatment 8-concommitant consumption of drugs interacting with vitamin d levels (i.e phenytoin, phenobarbital, carbamazepin, theophylline) 9-unable to give consent to participate in the study or inability to complete the study 10-Death of the patient

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Hormozgan University of Medical Sciences

Street address
Shahid Mohammadi Hospital- Research and Technology Department

City
Bandar Abbas

Postal code
7919915519

Approval date
2013-05-22, 1392/03/01

Ethics committee reference number
1156

Health conditions studied

1

Description of health condition studied
Smnear positive pulmonary tuberculosis

ICD-10 code
A15.0

ICD-10 code description
Tuberculosis of lung, confirmed by sputum microscopy with or without culture

Primary outcomes

1

Description
Sputum conversion

Timepoint
At the initiation of treatment and six months after

Method of measurement
Sputum smear

Secondary outcomes

empty

Intervention groups

1

Description
Control Group: Placebo (manufactured by DANA pharmaceutics) for 6 months PO for 6 months.

Category
Treatment - Drugs

2

Description
case group: vit D3 capsule: 50000IU/day PO,(manufactured by Dana Pharmaceutics) for 6 months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Bandar Abbas Health center, Pulmonary disease center
Full name of responsible person
Street address
City
Bandar Abbas

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hormozgan University of MedicalSciences, research and technology department
Full name of responsible person
Mirza ali Nazarnejhad
Street address
Jomhouri Blvd, Shahid Mohammadi hospital, research and technology department
City
Bandar abbas
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hormozgan University of MedicalSciences, research and technology department
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty