

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of high dose vitamin D as adjunctive therapy on clinical outcomes and prognostic biomarkers in patients with Acute Exacerbation of Chronic Obstructive Pulmonary Disease.

Protocol summary

Summary

Within the last decade, immunomodulatory properties of vitamin D is showed .vitamin D triggers effective antimicrobial pathways against bacterial, fungal and viral pathogens witch play capital role in AECOPD which responsible for majority of COPD burden and hospitalization. Vitamin D deficiency (VDD) is a pandemic in the world and especially in COPD patient. Previous study showed protective effects of vitamin D in vitamin D deficient COPD patient, cost effectiveness and most appropriate pharmacokinetic of single high dose vitamin D intramuscularly as a treatment for vitamin D deficiency. We will perform a randomized, intervention study on 70 AECOPD hospital admitted patients, aged 40 years and older with VDD. Participants will be recruited after admission and allocated in a 1:1 ratio to receive vitamin D 300.000 or not. Participants will receive a diary card to register the event such as hospital admission and oxygen-ventilator day and changes in medication especially corticosteroid and antibiotic use during 3 month study period. Assessment include; resolution of inflammatory response either systemic (hsCRP-IL6) or pulmonary (IL8) in day 1 and 5. And physical performance test hand grips strength and clinical parameters such as MMRC and SGRQ (day 1 and 90). In contrast to earlier studies that used frequent, low and oral vitamin D regimens, we will use a single high dose of vitamin D intramuscular. Secondly, our fine period assessment (day 1 and 5)in contrast to earlier study (coarse time assessment) better evaluate vitamin D role on resolution of inflammation in AECOPD.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031425726N4**

Registration date: **2016-05-15, 1395/02/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-15, 1395/02/26

Registrant information

Name

Farzaneh Dastan

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

resaerch council of School of Pharmacy, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2016-04-17, 1395/01/29

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of high dose vitamin D as adjunctive therapy on

clinical outcomes and prognostic biomarkers in patients with Acute Exacerbation of Chronic Obstructive Pulmonary Disease.

Public title
Effect in recovery of inflammation and respiratory function in chronic obstructive pulmonary disease.

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria include; Vitamin D deficiency (serum 25(OH)D < 50 nmol/l) Postbronchodilator FEV1/FVC < 0.70, FEV1 < 80 % and diagnosis acute exacerbation of COPD confirmed by a physician Age ≥ 40 years Written informed consent Ability to comply with all study requirements Exclusion criteria include Severe vitamin D deficiency (serum 25(OH)D < 15 nmol/l), Use of a supplement containing more than 400 IU vitamin D per day Diagnosed asthma Diagnosed osteoporosis Self-reported history of hypercalcaemia or nephrolithiasis Self-reported presence of sarcoidosis Diagnosed chronic kidney disease stage 4 or higher (eGFR ≤ 29 ml/min/1.73 m²) liver insufficiency child pough class B or C Interfering malignant diseases Life expectation of less than 1 year on the basis of concurrent disease Current participation in a clinical rehabilitation program Pregnant or lactating women, or subjects who intend to become pregnant within the study period Potentially unreliable patients and those judged by the investigator to be unsuitable for the study Serious mental impairment i.e. preventing to understand the study protocol or comply with the study aim.

Age
From **40 years** old to **139 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

pharmacy and nursing and midwifery faculty, s Ethics committee

Street address

Niayesh Highway, Valiasr Ave, Tehran, Iran

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Postal code

1991953381

Approval date

2016-03-01, 1394/12/11

Ethics committee reference number

IR.SBMU.PHNM.1394.306

Health conditions studied

1

Description of health condition studied

acute exacerbaton of chronic obstructive lung disease

ICD-10 code

J44.1

ICD-10 code description

Chronic obstructive pulmonary disease with acute exacerbation, unspecified

Primary outcomes

1

Description

interleukin 6 and interleukin 8 and hsCRP LEVEL

Timepoint

day of admission and day 5

Method of measurement

ELISA

Secondary outcomes

1

Description

modified medical research council dyspnea scale

Timepoint

day of admission-day 5 and month 3 after inclusion to study

Method of measurement

questionnaire

2

Description

st george respiratory questionnaire quality of life

Timepoint

day 1 and 90 after admission

Method of measurement

Patient-reported Outcomes & questionnaire fill out

Intervention groups

1

Description

control group receives standard therapy

Category

N/A

2

Description

Intervention group receive vitamin D 300,000 IU intramuscularly in addition to standard therapy of AECOPD

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital, Shaheed Beheshti Medical University

Full name of responsible person

dr farzaneh dastan

Street address

Masih Daneshvari Hospital, Darabad Street

City

drug care unite

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research council of School of Pharmacy, Shahid Beheshti University

Full name of responsible person

dr Nima Naderi

Street address

Niayesh Highway, Valiasr Ave, Tehran, Iran

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Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research council of School of Pharmacy, Shahid Beheshti University

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

Name of organization / entity

faculty of pharmacy Shahid Beheshti University of Medical Sciences

Full name of responsible person

dr Seyed mouhmad hassn pourrashid

Position

Doctor of Pharmacy

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Position

Clinical Pharmacy (Pharmacotherapy) specialist.associate professor

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Person responsible for updating data

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Full name of responsible person

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Other areas of specialty/work

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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