Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 ofMedical 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
Effecct in recovery of inflamation 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 faculti,s Ethics committee
Street address
Niayesh Highway, Valiasr Ave, Tehran, Iran
City
Tehran
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 ecxacerbation of chronic obstroctive 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 admision and day 5
Method of measurement
ELISA

Secondary outcomes

1

Description
modified medical research council dyspnea scale
Timepoint
day of admision-day 5 and mounth 3 after inclusion to study
Method of measurement
questionaire

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 recieves standard therapy
Category
N/A

2

Description
Intervention group recieve vitamin D 300,000 IU intramuscullaryin 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
City
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
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Doctor of Pharmacy
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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person

dr Seyed mouhammad hasan pourrashid

Position

resident of clinical pharmacy

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