Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Study of the effect of vitamin D supplementation on outcome and prognostic biomarkers of VAP in patient with vitamin D deficiency

Protocol summary

Summary

Objectives: The effect of vitamin D 3 supplementation on clinical outcomes and prognostic biological indicators (eg, CRP, interleukin-6 and Procalcitonin) in mechanically ventilated patients with pneumonia that suffered from deficiency of vitamin D3. Design: This study will be done as a randomized clinical trial on 46 patients suffering from ventilator associated pneumonia admitted to the intensive care unit of Loghman Hakim and Shohadaye Tajrish hospitals. Setting and conduct: Patients during the first 48 hours after the diagnosis of pneumonia caused by mechanical ventilation were enrolled and randomly divided into 2 groups. One group of patients will receive 300,000 IU of vitamin D3 as intramuscular injection and the other group will receive placebo. On the first day of study level of 25-hydroxy vitamin D3, CRP, IL-6, Procalcitonin and parameters included age, sex, underlying disease, medications, SOFA score and CPIS score, liver function and renal failure, clinical findings of pneumonia, CBC, body temperature, vital signs and location will be examined and recorded. Following the treatment, the daily CBC, body temperature and respiratory secretions been assessed and recorded. On the seventh day of treatment, the level of 25-hydroxyvitamin D3, CRP, IL-6, Procalcitonin, CPIS score and SOFA score were measured, and during this period the patient's treatment will modify according to the results of cultures of lung secretions and clinical changes. Finally in the 28th day of study evaluation of 28 day mortality will be performed for all patients. Participants including major eligibility criteria: Patients over 18 years old, that clinically and based on the following criteria have been diagnosed with VAP (During the first 48 hours of diagnosis): The presence of new or progressive infiltration on the patient's chest radiograph that occur 48-72 hours after initiation of mechanical ventilation, While two of the following symptoms must be present with it: Fever over 38 ° C; leukocytosis or leukopenia (white blood cell count greater than 12,000 per µL of blood or less than 4000 per µL of blood) and purulent pulmonary secretions. The exclusion criteria included: Stage3 or more chronic kidney problems; liver problems with CHILD-PUGH stage B or C; history of cancer within the last 3 months, or currently taking chemotherapy drugs; patients with immune deficiency; pancreatitis; other infections, concurrently with pneumonia caused by mechanical ventilation, patients with VAP that the vitamin D levels are normal and Coagulopathy. Intervention: One group of patients will receive 300,000 IU of vitamin D3 as intramuscular injection and the other group will receive placebo. Main outcome measures: Level of 25-hydroxy vitamin D3, CRP, IL-6, Procalcitonin, SOFA score and CPIS score and outcome of the 28-day.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014112920134N1**
Registration date: **2015-01-31, 1393/11/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-01-31, 1393/11/11

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete
Funding source
Shahid Beheshti University of Medical Sciences, School of Pharmacy

Expected recruitment start date
2014-09-23, 1393/07/01
Expected recruitment end date
2015-06-21, 1394/03/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study of the effect of vitamin D supplementation on outcome and prognostic biomarkers of VAP in patient with vitamin D deficiency

Public title
Evaluation of vitamin D supplementation on outcome of patients with ventilator associated pneumonia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Patients over 18 years old, that clinically and based on the following criteria have been diagnosed with VAP (During the first 48 hours of diagnosis): The presence of new or progressive infiltration on the patient's chest radiograph that occur 48-72 hours after initiation of mechanical ventilation, While two of the following symptoms must be present with it: Fever over 38 ° C; leukocytosis or leukopenia (white blood cell count greater than 12,000 per µL of blood or less than 4000 per µL blood) and purulent pulmonary secretions. Exclusion criteria: Stage3 or more chronic kidney problems; liver problems with CHILD-PUGH stage B or C; history of cancer within the last 3 months, or currently taking chemotherapy drugs; patients with immune deficiency; pancreatitis; other infections, concurrently with pneumonia caused by mechanical ventilation, patients with VAP that the vitamin D levels are normal and Coagulopathy.
Age
From **17 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee Shahid Beheshti University of Medical Sciences, School of Pharmacy
Street address
"Vali Asr Avenue, below the Niayesh highway, Tehran, Zip Code: 1991953381"
City
Tehran
Postal code
1991953381
Approval date
2014-09-10, 1393/06/19
Ethics committee reference number
285

Health conditions studied

1

Description of health condition studied
ventilator associated pneumonia
ICD-10 code
J13
ICD-10 code description
Pneumonia due to Streptococcus pneumoniae

2

Description of health condition studied
ventilator associated pneumonia
ICD-10 code
J16
ICD-10 code description
Pneumonia due to other infectious organisms, not elsewhere classified

3

Description of health condition studied
ventilator associated pneumonia
ICD-10 code
J14
ICD-10 code description
Pneumonia due to Haemophilus influenzae

4

Description of health condition studied
ventilator associated pneumonia
ICD-10 code
J15
ICD-10 code description
Bacterial pneumonia, not elsewhere classified

5

Description of health condition studied
ventilator associated pneumonia
ICD-10 code
J17
ICD-10 code description
Pneumonia in diseases classified elsewhere

6

Description of health condition studied
ventilator associated pneumonia
ICD-10 code
J18
ICD-10 code description
Pneumonia, organism unspecified

Primary outcomes

1

Description
Procalcitonin plasma level
Timepoint
Day 1 and 7 of study
Method of measurement
Plasma level that measured with electrochemiluminescence and reported as ng/ml

2

Description
C-reactive protein plasma level
Timepoint
Day 1 and 7 of study
Method of measurement
Plasma level that measured with elisa kit and reported as mg/L

3

Description
Interleukin-6 plasma level
Timepoint
Day 1 and 7 of study
Method of measurement
Plasma level that measured with elisa kit and reported as pg/ml

4

Description
Vitamin D plasma level
Timepoint
Day 1 and 7 of study
Method of measurement
Plasma level that measured with elisa kit and reported as ng/ml

Secondary outcomes

1

Description
Outcom at 28 days
Timepoint
Day 28
Method of measurement
Evaluation of mortality

Intervention groups

1

Description
Intramuscular injection of 300,000 IU of vitamin D in the treatment group as a single dose on the first day of treatment only
Category
Treatment - Drugs

2

Description
Intramuscular injection of vitamin D placebo in the control group as a single dose on the first day of study
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada-e-Tajrish hospital
Full name of responsible person
"Dr Fatemi Alireza"
Street address
"Shahrdari street, Tajrish square, Tehran".
City
Tehran

2

Recruitment center
Name of recruitment center
Loghman-e-hakim hospital
Full name of responsible person
"Dr Shokoohi Shervin"
Street address
"Makhsoos street, Kamali street, Lashkar crossroad, South Kargar Avenue, Tehran".
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Chancellor for research, shahid beheshti medical university
Full name of responsible person
"Dr Zarghi Afshin"
Street address
"Shahid Abas Arabi street, next to Taleghani hospital, Yaman street, Chamran highway, Tehran".
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Chancellor for research, shahid beheshti medical 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
Shahid Beheshti University of Medical Sciences, School of Pharmacy
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"Salamzadeh Jamshi"
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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*