

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

Name

Amir Ebrahim Miroliaee

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
School of Pharmacy

Country

Iran (Islamic Republic of)

Phone

+98 21 8887 3704

Email address

amir.e.miroliaee@sbm.ac.ir

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

Full name of responsible person

"Salamzadeh Jamshi"

Position

Professor of clinical Pharmacy Department

Other areas of specialty/work**Street address**

"Vali Asr Avenue, below the Niayesh highway, Tehran, Zip Code: 1991953381"

City

Tehran

Postal code**Phone**

+98 21 8887 3704

Fax**Email**

j.salamzadeh@yahoo.com

Web page address

Person responsible for scientific

inquiries

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences, School of Pharmacy

Full name of responsible person

"Sahraee Zahra"

Position

Clinical Pharmacy Specialist

Other areas of specialty/work**Street address**

"Vali Asr Avenue, below the Niayesh highway, Tehran, Zip Code: 1991953381"

City

Tehran

Postal code**Phone**

+98 21 8887 3704

Fax**Email**

zahra.sahraee@yahoo.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Shahid Beheshti University of Medical Sciences, School of Pharmacy

Full name of responsible person

"Miroliaee Amir Ebrahim"

Position

Resident of Clinical Pharmacy

Other areas of specialty/work**Street address**

"Vali Asr Avenue, below the Niayesh highway, Tehran, Zip Code: 1991953381"

City

Tehran

Postal code**Phone**

+98 21 8887 3704

Fax**Email**

aamthunderbird@gmail.com

Web page address

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

