Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

Effects of ultra dose vitamin D supplementation on remission, morbidity and mortality of ventilator associated pneumonitis (VAP) patients: A Randomized Controlled Trial study.

Protocol summary

Study aim

Evaluate the effects of ultra dose vitamin D supplementation on changing the Pneumonia Severity Index (PSI) score, mortality risk by calculating the Acute Physiology and Chronic Health Enquiry (APACHE-II) score and morbidity by calculating the Sequential Organ Failure Assessment (SOFA) score in VAP patients in intensive care unit (ICU).

Design

Randomized, double blind, parallel group trial. Randomization will be centralised and computerised with concealed randomisation sequence will be carried out at an external site, samle size:42.

Settings and conduct

Study will be done in the Shahid Kamyab Hospital of Mashhad city with double blinded (participants and investigator) method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: PSI>51, serum vitamin D<20 ng/ml, stable hemodynamic, absence of consumption of hydrochlorothiazide, digoxin and magnesium including anti-acid drugs, ability to be nourished enterally during the first 24 to 48 hours of admission,serum calcium levels below10.8 mg/dl at the admission, absence of history of vitamin D supplementation (>1000 units) in the past 4 months, absence of these disease: hyperparathyroidism, nephrolithiasis, sarcoidosis, chronic kidney disease, cirrhosis, metabolic diseases, acquired immune deficiency syndrome, cardiovascular disease, diabetes mellitus, cancers and autoimmune diseases, not participating in any other RCTs, not to be pregnant, signing the consent form by family of the patients. Exclusion criteria: Death before 7 days after intervention, inability to be iterally fed after 5 days of intervention, hazardous or forbidden supplementation for the patient and presence of other types of pneumonitis.

Intervention groups

Intervention and control groups will be supplemented by either 2 cc/day vitamin D with the dose of 100000 units and 2 cc/day placebo for 5 days.

Main outcome variables

Changing PSI, morbidity and mortality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200324046844N1**
Registration date: **2020-05-19, 1399/02/30**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-19, 1399/02/30**
Update count: **0**

Registration date

2020-05-19, 1399/02/30

Registrant information

Name

Seyed abolfazl Azariyan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4255 8194

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-29, 1399/02/10

Expected recruitment end date

2020-10-31, 1399/08/10

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of ultra dose vitamin D supplementation on remission, morbidity and mortality of ventilator associated pneumonitis (VAP) patients: A Randomized Controlled Trial study.

Public title
Ultra dose vitamin D supplementation in ventilator associated pneumonitis (VAP) patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pneumonia Severity Index (PSI) score above 51 The level of vitamin D below 20 ng/ml at the admission to the hospital Absence of hypercalcemia at the admission to the hospital (calcium concentration above 10.8 mg/dl) Stable hemodynamic status Not consuming hydrochlorothiazide, digoxin and magnesium containing antacids Absence of history of consuming vitamin D during the past four months with the dose above 1000 units Able to be be fed enterally at the 24 to 48 hours from the admission time Signing the consent form by the family of patients Absence of any of these disease: hyperparathyroidism, nephrolithiasis, sarcoidosis, chronic kidney disease, cirrhosis, metabolic diseases, acquired immune deficiency syndrome (AIDS), cardiovascular disease, diabetes mellitus, cancers and autoimmune diseases Not being pregnant Not involved in other research projects
Exclusion criteria:
Presence of other types of pneumonitis Dying earlier than 7 days of intervention Presence of any condition leading to enteral feeding disruption during the first 5 days of intervention If the supplementation is thought to be hazardous or being forbidden by the general practitioner
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization method will be used to randomize every patient individually by usage of www.sealedenvelope.com cite. Then, the computer software will be used. The random sequence will be built by the software.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this RCT, the participants, investigator, healthcare providers (including the pulmunologist who visits the patient and the nurses who provide vitamin D or placebo to the patient), data analyser and the outcome assessor would not informed about the provided intervention to the patient (vitamin D or placebo).
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Human Research Ethics Committee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, Opposite Palestine St., Zandani St.
City
Shiraz
Province
Fars
Postal code
14336-71348
Approval date
2020-02-26, 1398/12/07
Ethics committee reference number
IR.SUMS.REC.1398.1382

Health conditions studied

1

Description of health condition studied
Ventilator associated pneumonitis (VAP)
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Morbidity and organ failure calculated by the Sequential Organ Failure Assessment (SOFA) score, mortality risk

assessed by the Acute Physiology and Chronic Health Enquiry (APACHE-II) score and change in the Pneumonia Severity Index (PSI) score

Timepoint

Completing the questionnaires and telephone contact about death after releasing from hospital in the 28 days after intervention

Method of measurement

SOFA, APACHE-II and PSI questionnaire and mortality numbers by telephone for released patients

Secondary outcomes

1

Description

SOFA, APACHE-II and mortality rate

Timepoint

On day 0, 7 and 14 of the intervention

Method of measurement

On day 0, 7 and 14 of the beginning of the intervention we will complete the SOFA & APACHE-II questionnaire and on day 28 we will ask the family of the patients for death after releasing from hospital.

Intervention groups

1

Description

Intervention group: 2 cc/day vitamin D with the dose of 100000 units orally for five days from Zahravi drug company

Category

Treatment - Other

2

Description

Control group: 2 cc/day olive oil as placebo for five days, orally

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Kamyab Hospital of Mashhad city

Full name of responsible person

Behrooz Momeni

Street address

Fadaiyan Eslam Ave., near to Nakhrisi Crossroads

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Province

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2587413695

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Abolfazl Azariyan

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Full Professor
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Person responsible for updating data

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Email
abolfazlazariyan1@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data about the outcomes are available
When the data will become available and for how long
3 months after publication
To whom data/document is available
People who are working in academic institutions
Under which criteria data/document could be used
Statistical analysis are available.
From where data/document is obtainable
Asking from Dr. Zohreh Mazloom and Seyed Abolfazl Azariyan by sending Email to these adresses: zohres.mazloom@gmil.com and Abolfazlazariyan1@gmail.com
What processes are involved for a request to access data/document
Email may be answered after 1 months of sending Email.
Comments