

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Assessment of the effect of Vit D supplementation on oxidative stress markers and weaning from mechanical Ventilatory Traumatic patients

Protocol summary

Study aim

Determining the effect of vitamin D supplements on oxidative stress markers and weaning from mechanical Ventilatory Traumatic patients admitted to intensive care unit

Design

In this randomized clinical trial, 72 patients, 18-65 years old, undergoing mechanical ventilation in the intensive care unit, were randomly divided into two intervention groups and one control group.

Settings and conduct

This single-blind study will be performed on patients undergoing mechanical ventilation in the intensive care unit of Urmia Imam Khomeini Hospital. Patients will be randomly assigned to 3 groups (the first group will be vitamin D, the second group will be vitamin D and the third control group). The study will be single-blind so that patients will not be informed about which groups will be assigned.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients aged 18-65 years undergoing mechanical ventilation with a serum vitamin D level of between 10-30 ng/ml. Exclusion criteria: patients with chronic and acute renal failure, hemodialysis or peritoneal dialysis and GCS less than 9.

Intervention groups

Patients in the intervention groups will receive 50000 units of vitamin D for 6 consecutive days or vitamin D 300,000 units in muscle once. The control group will not receive any intervention.

Main outcome variables

SOFA(Sequential Organ Failure Assessment Score); Mechanical ventilation duration; Admitted duration; Mortality; Body composition; IL6 serum level; 7- TAC (Total Antioxidant Capacity) serum level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171221037983N1**
Registration date: **2018-01-11, 1396/10/21**
Registration timing: **registered_while_recruiting**

Last update: **2018-01-11, 1396/10/21**

Update count: **0**

Registration date

2018-01-11, 1396/10/21

Registrant information

Name

Mohammad Amin Valizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9935

Email address

valizademohammadamin@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the effect of Vit D supplementation on oxidative stress markers and weaning from mechanical Ventilatory Traumatic patients

Public title

Assessment of the effect of Vit D supplementation in mechanical Ventilatory Traumatic patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All mechanical Ventilatory Traumatic patients admitted to intensive care unit The age group 18-65 years Vit D serum level between 10-3 ng/ml Minimum length of stay 7 days in ICU

Exclusion criteria:

Patients with chronic and acute renal failure Patients under hemodialysis or peritoneal dialysis GCS<9

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **72**

More than 1 sample in each individual

Number of samples in each individual: **1**

Each participant will provide a sample for study.

Randomization (investigator's opinion)

Randomized

Randomization description

Using statistical software, patients will be randomly assigned to the intervention groups and control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

this study will be carried out single blind so that the patient is unaware.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Urmia University of Medical Sciences

Street address

Ershad Ave, Modarres Blvd, Imam Khomeini Hospital, Urmia

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Urmia

Province

West Azarbaijan

Postal code

81351-57157

Approval date

2017-12-13, 1396/09/22

Ethics committee reference number

IR.UMSU.REC.1396.288

Health conditions studied**1****Description of health condition studied**

Traumatic patients

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder (PTSD)

Primary outcomes**1****Description**

Oxidative Stress: determining the total antioxidant capacity and IL6 serum levels

Timepoint

Baseline-7 days after intervention

Method of measurement

ELISA Test

2**Description**

SOFA (Sequential organ failure assessment score)

Timepoint

Baseline-7 days after intervention

Method of measurement

checklist

Secondary outcomes**1****Description**

Body composition

Timepoint

Baseline- after 7 days from intervention

Method of measurement

body Analyzer Inbody

2**Description**

mortality

Timepoint

end of study

Method of measurement

dead or live

Intervention groups

1

Description

Intervention group: 50000 IU oral Vitamin D for 6 consecutive days

Category

Treatment - Drugs

2

Description

Intervention group: Vitamin D 300,000 units are muscle and in a single dose

Category

Treatment - Drugs

3

Description

Control group: Patients will not receive the any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Dr. Mohammad Amin Valizade

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valizadeh.ma@umsu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr.Iraj Mohebbi

Street address

Resalat Ave, Urmia University of Medical Sciences, Urmia

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mohebbi.i@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Mohammad Amin Valizade

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidentiality of Participants Information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The results will be shared on paper.

When the data will become available and for how long

One year after the completion of the project.

To whom data/document is available

Researchers

Under which criteria data/document could be used

Reaserchers

From where data/document is obtainable

Emial: valizadeh.ma@umsu.ac.ir

What processes are involved for a request to access data/document

Request access via email

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Afsoon Eivazlou

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

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