

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Feb 2026

Effect of high dose Vitamin D3 on mortality, morbidity, length of stay in ICU and mechanical ventilation duration in pulmonary ICU patients.

Protocol summary

Summary

The overall objective of this study is to investigate the effect of high-dose vitamin D3 on mortality, complications, length of stay in ICU and mechanical ventilation duration in pulmonary ICU patients. The specific objectives are: Comparison of length of stay in the ICU, mechanical ventilation duration, mortality and morbidity rates and in-hospital complications in two study groups. This study is a double-blind, controlled clinical trial. Inclusion criteria consist of: ICU admissions with mechanical ventilation, length of stay in ICU more than 48 hours and 25-hydroxy vitamin D levels less than 20 ng/ml. Exclusion criteria consist of: age younger than 18 years on admission to ICU, length of stay in ICU less than 48 hours; 25-hydroxy vitamin D levels more than 20 ng/ml. For patients in the intervention group 600,000 units of intramuscular vitamin D3 will be injected without any intervention in control group. Total and ionized calcium and serum 25-hydroxy vitamin D levels in the third, seventh and fourteenth days after administration of vitamin D3 will be measured and length of stay in ICU, duration of mechanical ventilation, mortality and morbidity rates according to their records will be analyzed and compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014050517583N1**
Registration date: **2015-02-19, 1393/11/30**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-19, 1393/11/30

Registrant information

Name

Haleh Mikaeili

Name of organization / entity

Tabriz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 413347054

Email address

mikaeilih@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2015-01-20, 1393/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of high dose Vitamin D3 on mortality, morbidity, length of stay in ICU and mechanical ventilation duration in pulmonary ICU patients.

Public title

Effect of high dose Vitamin D on mortality and morbidity in pulmonary ICU patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ICU admissions with mechanical ventilation, ICU length of stay more than 48 hours; 25-hydroxy vitamin D levels less than 20 ng/ml. Exclusion

criteria:Age Younger than 18 years on admission to ICU;
ICU length of stay less than 48 hours ; 25-hydroxy
vitamin D levels More than 20 ng /ml.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Tabriz University of Medical Sciences Ethics
Committee

Street address

Golgasht street, Tabriz University of Medical Sciences
,central building

City

Tabriz

Postal code

Approval date

2013-12-02, 1392/09/11

Ethics committee reference number

5/4/8145

Health conditions studied

1

Description of health condition studied

Respiratory faillure

ICD-10 code

J96

ICD-10 code description

Respiratory failure, not elsewhere classified

Primary outcomes

1

Description

calcium total and ionized

Timepoint

0,3,7,14 days after vitd injection

Method of measurement

serum level

2

Description

25OH Vit D

Timepoint

0,3,7,14 days after vitd injection

Method of measurement

Serum level

3

Description

Duration of mechanical ventilation

Timepoint

Until discharge from hospital

Method of measurement

Records of patient

Secondary outcomes

1

Description

Mortality

Timepoint

Until discharge from hospital

Method of measurement

Observations and records of patient

2

Description

Hospitalization days

Timepoint

Until discharge from hospital

Method of measurement

Observations and records of patient

3

Description

Hospital complications

Timepoint

Until discharge from hospital

Method of measurement

Observations and records of patient

Intervention groups

1

Description

In intervention group single dose of 600,000 units of vitamin D3 will be injected intramuscular.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Dr mikaeili Haleh

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research deputy of Tabriz University of Medical Sciences

Full name of responsible person

Dr. Hassan Soleimanpour

Street address

Golgasht Street ,Tabriz University of Medical Sciences ,central building II,third floor

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research deputy of Tabriz University of Medical Sciences

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

Tabriz medical siense university

Full name of responsible person

Dr. Mikaeili-haleh

Position

Associate Professor

Other areas of specialty/work

Street address

Emam Reza hospital, Golgasht Ave

City

Tabriz

Postal code

Phone

+98 41 3335 7310

Fax

Email

Mikaeilih@tbzmed.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz medical science university

Full name of responsible person

Dr Mikaeili Haleh

Position

Associate Professor

Other areas of specialty/work

Street address

Emam Reza hospital, Golgasht Ave

City

Tabriz

Postal code

Phone

+98 41 3335 7310

Fax

Email

Mikaeilih@tbzmed.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz medical scince university

Full name of responsible person

Dr Mikaeili Haleh

Position

Associate Professor

Other areas of specialty/work

Street address

Emam Reza hospital, Golgasht Ave

City

Tabriz

Postal code

Phone

+43 3357 310

Fax

Email

Mikaeilih@tbzmed.ac.ir

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

Data Dictionary

empty