Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Comparing effect of high dose vitamin D and placebo on insulin resistance in critically ill patients

Protocol summary

Summary

The main goal of the study is comparing effect of high dose vitamin D and placebo on stress-induced hyperglycemia in critically ill patients. Fifty patients with diagnosis of stress-induced hyperglycemia during the first 24 hours of ICU admission will be recruited. Included patients will be assigned to vit D or placebo group based on the block randomization method. Patients in the vit D and placebo group will receive either 600000 IU vitamin D3 or placebo as single IM injection respectively at time of diagnosis of stress-induced hyperglycemia. Vitamin D3 as 300000 IU ampule and its placebo will be prepared by Darou-Pakhsh Pharmaceutical Company, Tehran, Iran. A 10-ml venous blood sample will be collected from each patient at baseline (at admission time before intervention) and at day 7. Serum levels of 25 (OH) vitamin D3, adiponectin, glucose and insulin will be measured within these samples. In addition HOMA-IR (Homeostasis Model Assessment-Insulin Resistance) will be calculated for all the patients at baseline and day 7. Finally, based on the collected data, effect of vitamin D and placebo administration on the serum levels of vitamin D, adiponectin (as a marker of insulin resistance), HOMA-IR will be compared at the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014061218069N1**
Registration date: **2014-10-06, 1393/07/14**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-10-06, 1393/07/14

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-03-30, 1393/01/10

Expected recruitment end date

2016-03-29, 1395/01/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effect of high dose vitamin D and placebo on insulin resistance in critically ill patients

Public title

Effect of high dose vitamin D on blood glucose in critically ill patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: - Critically ill patients aged between 18-65 years old with diagnosis of stress-induced hyperglycemia during the first 24 hours of intensive care unit (ICU) admission will be recruited. Exclusion criteria:

Patients with following characteristics will be excluded: Diabetic patients, hemoglobin (Hbg) A1C>7.5, positive history of hypersensitivity to vitamin D or its analogues, hypercalcemia, any contraindication for intramuscular (IM) injection, current use of corticosteroids or any drugs affecting patients' blood glucose.

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Included patients will be assigned to the intervention (Vit D) or placebo group based on the block randomization method. Vitamin D and its placebo will be prepared by the pharmaceutical company with same packaging and drug formulation properties. The researchers, ICU physicians and patients are blinded and drug will be distributed by the hospital pharmacy department.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences

Street address
Ghods Ave. Tehran, Iran

City
Tehran

Postal code

Approval date
2014-03-10, 1392/12/19

Ethics committee reference number
93-2-33-25718

Health conditions studied

1

Description of health condition studied
Hyperglycemia

ICD-10 code
R73

ICD-10 code description
Elevated blood glucose level

Primary outcomes

1

Description
Plasma insulin

Timepoint
During 24 hours of ICU admission and 7 days after intervention

Method of measurement
Elisa kit

2

Description
Plasma glucose

Timepoint
During 24 hours of ICU admission and 7 days after intervention

Method of measurement
Elisa Kit

3

Description
Serum level of 25 (OH) vitamin D3

Timepoint
During 24 hours of ICU admission and 7 days after intervention

Method of measurement
Elisa kit

4

Description
Adiponectin

Timepoint
During 24 hours of ICU admission and 7 days after intervention

Method of measurement
Elisa kit

Secondary outcomes

empty

Intervention groups

1

Description
Single IM injection of 600000 IU vitamin D3 in intervention group (Two 300000 IU vitamin D3 ampules , each one contains 1 ml of drug)

Category
Treatment - Drugs

2

Description
IM injection of 2 placebo ampules (each one contains 1 ml Placebo)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Dr Hossein Khalili
Street address
Keshavarz AVE, Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Tehran University of Medical Sciences
Full name of responsible person
Masoud Yunesian
Street address
Ghods Ave
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Tehran 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
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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