# 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**

**Name**
Nafiseh Sadat Alizadeh
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Tehran University of Medical Sciences
**Country**
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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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## Person responsible for scientific inquiries

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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*