Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of vitamin D3 supplementation on AKI risk in multiple trauma patients admitted to ICU with elevated CPK level

Protocol summary

Study aim
investigation of the nephroprotective effect of Vitamin D in multiple trauma patients with elevated CPK levels

Design
Randomized, parallel group trial, not blinded, single center design of 30 patients divided into 2 groups of 15(control and intervention)

Settings and conduct
Patients with increased serum CPK levels admitted to the intensive care unit of Imam Hussein Hospital in Tehran, are divided in two groups of intervention and control.

Participants/Inclusion and exclusion criteria
Inclusion: Patients over 18 with at least two distinct injuries who were diagnosed with multiple trauma Serum creatinine phosphate level higher than or equal to 5 times normal, in the first 48 hours of admission to ICU. Exclusion: Patients with a recent history of myocardial infarction (within one week before the trauma) pregnancy or lactation direct kidney trauma, patients who received more than 2000I.U of vitamin D3 per day during the past week, total calcium level above 9 mg/dl or phosphate level above 6 mg/dl at the time of admission, history of organ transplantation or long-term use of immunosuppressive drugs patients with a history of diseases related to vitamin D3 levels, such as primary parathyroid, metabolic bone disease, or acute renal failure

Intervention groups
Intervention: Patients admitted to ICU who receive 300,000 i.u. of vitamin D3 by intramuscular injection. Control group: Patients admitted to ICU without receiving vitamin D3 for observation.

Main outcome variables
CPK changes between two groups

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120703010178N23**
Registration date: **2021-01-16, 1399/10/27**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-16, 1399/10/27**
Update count: **0**

Registration date
2021-01-16, 1399/10/27

Registrant information

Name
Mohammad Sistanizad

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 8820 0087

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sistanizadm@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-01-21, 1398/11/01

Expected recruitment end date
2021-01-20, 1399/11/01

Actual recruitment start date
2020-01-21, 1398/11/01

Actual recruitment end date
2021-01-20, 1399/11/01

Trial completion date
2021-02-03, 1399/11/15

Scientific title
The effect of vitamin D3 supplementation on AKI risk in multiple trauma patients admitted to ICU with elevated CPK level

Public title
The effect of vitamin D3 supplementation on AKI risk in multiple trauma patients admitted to ICU with elevated CPK level
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
patients over 18 patients with at least two distinct injuries who were diagnosed with multiple trauma Serum creatinine phosphate level higher than or equal to 5 times normal, from admission to the intensive care unit up to 48 hours later
Exclusion criteria:
Patients with a recent history of myocardial infarction (within one week before the trauma) pregnancy or lactation, patients with direct kidney trauma high serum vitamin D3 levels patients who received more than 2000I.U of vitamin D3 per day during the past week, total calcium level above 9 mg/dl or phosphate level above 6 mg/dl at the time of admission, history of organ transplantation or long-term use of immunosuppressive drugs, patients with a history of diseases related to vitamin D3 levels, such as primary parathyroid, metabolic bone disease, or acute renal failure
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **30**
Actual sample size reached: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
The randomization was done by block randomization method using a randomization table made with statistical software with four blocks and individual randomization unit. To hide this table, there is only one copy of this table without specifying the study groups that are maintained by the study host in the center
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Beheshti University
Street address
Shahid Beheshti University of Medical Sciences, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
193954719
Approval date
2018-07-02, 1397/04/11
Ethics committee reference number
IR.SBMU.PHARMACY.REC.1397.068

Health conditions studied

1

Description of health condition studied
Acute kidney injury (AKI) refers to an abrupt decrease in kidney function, resulting in the retention of urea and other nitrogenous waste products and in the dysregulation of extracellular volume and electrolytes
ICD-10 code
N.17.9
ICD-10 code description
Acute kidney injury

Primary outcomes

1

Description
prevalence of acute kidney injurie
Timepoint
within 2 weeks if ICU admission
Method of measurement
laboratory results of Serum creatinine; urine output

2

Description
serum creatine phosphokinase level
Timepoint
Daily from the ICU admission date up to either reaching normal level or 14 days.
Method of measurement
Serum CPK level laboratory measurement kits

Secondary outcomes

1

Description
follow up death for 28 days
Timepoint
since admitted it the ICU we follow up daily up to 28 days

Method of measurement
dead or alive before the 28 days follow up

Intervention groups

1

Description
Control group : patients with serum CPK level higher than 1000 I.U, no intervention, just observational.
Category
Other

2

Description
Intervention group: : patients with serum CPK level>1000 I.U, received a only a single dose of 300.000 I.U vitamin D3 intramuscular (IM) (darupakhsh company)
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
ICU, Imam Hussein Hospital
Full name of responsible person
Mohammad Sistanizad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Tahereh Shams
Street address
Faculty of pharmacy, no. 2660, Valiasr st., Tehran
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shamsijpr81@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Sistanizad
Position
Associate professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available