

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of single dose Vitamin D3 Injection on Kidney Function and Muscle Mass in Sepsis Patients

Protocol summary

Study aim

the aim of this study was to evaluate the hypothesis that injection of vitamin D3 300,000 IU compared with placebo can reduce the muscle mass loss process in patients with sepsis that were admitted to intensive care unit during hospitalization

Design

A 12-month prospective, randomized, double-blind study with two groups of case and control was conducted on 46 patients. patients were enrolled between December 2016 to November 2017

Settings and conduct

Emam Reza Hospital ICU, double blinded with placebo (1 cc Normalin Saline)

Participants/Inclusion and exclusion criteria

Inclusion criteria were Adult adult (≥ 18 yrs. old), critically ill patients within 24 hours of new-onset sepsis, who had three out of four criteria used to explain the systemic inflammatory response syndrome and who were admitted to Imam Reza Hospital, ICU and were expected to stay in the ICU for at least 48 hours from November 2016 to December 2017.

Intervention groups

24 patients received a single dose of 300,000 units VitD3 intramuscular injection

Main outcome variables

Sarcopenic Index, serum creatinine level, cystatin C serum level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150621022852N3**

Registration date: **2018-11-29, 1397/09/08**

Registration timing: **retrospective**

Last update: **2018-11-29, 1397/09/08**

Update count: **0**

Registration date

2018-11-29, 1397/09/08

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44429613

Email address

dr.s.asaadi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-11-01, 1395/08/11

Expected recruitment end date

2017-12-01, 1396/09/10

Actual recruitment start date

2016-11-01, 1395/08/11

Actual recruitment end date

2017-12-01, 1396/09/10

Trial completion date

2017-12-29, 1396/10/08

Scientific title

Effect of single dose Vitamin D3 Injection on Kidney Function and Muscle Mass in Sepsis Patients

Public title

effect of VitD3 on Kidney and Muscle in Sepsis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Critically ill patients within 24 hours of new-onset sepsis
Had three out of four criteria used to explain the

systemic inflammatory response syndrome Were expected to stay in the ICU for at least 48 hours

Exclusion criteria:

Acute Kidney Injury At least two risk factors for AKI
Rapidly changing GFR Rapidly changing serum creatinine
Rapidly changing cystatin C Pregnancy History of organ transplantation Hypercalcemic (ionized calcium>1.3 mmol/L) Maintenance renal replacement therapy
Platelets <30,000 per mm³ (Coagulopathy) International normalized ratio > 3 (Coagulopathy)

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **20**

Actual sample size reached: **22**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomized using a random number generator to get an IM injection of vitamin D3

Blinding (investigator's opinion)

Double blinded

Blinding description

Medical staff of ICU who were unaware of randomization injected vitaminD or placebo. Apart from vitD3 injection, other cilinical aspects were same between the two groups. As the patients and staff were blinded, we had no placebo effect

Placebo

Used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2018-04-07, 1397/01/18

Ethics committee reference number

IR.SBMU.REC.1397.002

Health conditions studied

1

Description of health condition studied

sepsis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

sarcopenic index

Timepoint

before the intervention, 14, 21 days after intervention

Method of measurement

serum creatinine-to-serum cystatin C ratio ×100

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 24 patients who recieved single dose 300,000 IU vit D3 IM

Category

Treatment - Drugs

2

Description

Control group: 22 patients who recieved placebo (1 cc Normal Saline)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman Hakim Hospital

Full name of responsible person

Mohammadreza Hajiesmaeli

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Makhsous st,South kargar st,Enghelab sq

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Afshin Zarghi
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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
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Latest degree
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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All information about the outcome of the study, will be

available after concealment.

When the data will become available and for how long

One year after the publication of the study results

To whom data/document is available

Researchers and university students of related fields can access the data after passing the administrative process.

Under which criteria data/document could be used

A study observer appointed by the ethics committee of Shahid Beheshti University of Medical Sciences can request to receive data after being unidentifiable in order to control the ethical aspects of the study.

From where data/document is obtainable

Head of the Center for Development of Clinical Research
- Management of Loghman Hakim Hospital

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

To receive data, please contact the Loghman Hakim Hospital Clinical Development Center. After obtaining permission from the Head of the Research Center and then the Loghman Hakim Hospital, access to patient information and study will be provided.

Comments