

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The Effect of single dose Vitamin D injection on renal function in Patients with Traumatic Injuries Hospitalized in Intensive Care Unit

Protocol summary

Study aim

The effect of single dose vitamin D injection on renal function in traumatic patients hospitalized in ICU

Design

A randomized clinical trial with a control group with parallel, double-blind, randomized groups, on 60 patients. Blocks of 4 random numbers are used for randomization.

Settings and conduct

Trauma patients in the intensive care unit of Ahvaz Golestan Hospital, if they meet the inclusion criteria and do not have the exclusion criteria, after obtaining written consent, they will be randomly divided into two groups A and B based on blocks of 4 random numbers. No one knows about it except the hospital pharmacist. Demographic information and trauma severity index, recorded at the beginning of hospitalization. Blood urea and creatinine levels are recorded daily, and anthropometric indices (BMI, abdominal circumference) are recorded on arrival and at the end of the 28th day or day of discharge. Both groups receive an intramuscular dose of 300,000 units of vitamin D or placebo during the first 24 hours of hospitalization. Duration of intensive care unit hospitalization, 28-day ventilator free days, and the discharge or death are recorded. Blinding: patients or families, nurses, researchers and statistical analysts will not know about the drug group, and drug injection will be done by hospital pharmacist.

Participants/Inclusion and exclusion criteria

Inclusion : trauma patient with a revised trauma score greater than or equal to 6 and over 18 years of age who has been hospitalized in the intensive care unit for at least 24 hours. **Exclusion :** having chronic kidney disease, autoimmune disease or cancer.

Intervention groups

The control group : received a single dose of intramuscular placebo on arrival to intensive care unit. The vitamin D group : received a single dose of intramuscular vitamin D on arrival to intensive care unit.

Main outcome variables

Cr Bun 24 hr urine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221121056570N2**

Registration date: **2023-08-15, 1402/05/24**

Registration timing: **prospective**

Last update: **2023-08-15, 1402/05/24**

Update count: **0**

Registration date

2023-08-15, 1402/05/24

Registrant information

Name

Mohsen Savaie

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3320 4536

Email address

savaie-m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-10-23, 1402/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of single dose Vitamin D injection on renal function in Patients with Traumatic Injuries Hospitalized in Intensive Care Unit

Public title

Vitamin D in Trauma

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Traumatic patient Age more than 18 Hospitalized in intensive care unit more than 24 hours Revised trauma score (RTS) ≥ 6 New trauma score (NTS) ≥ 8

Exclusion criteria:

Chronic renal failure Cancer Autoimmune disease Abstinece of patient

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done by the method of individual assigning of random numbers with blocks of 4. The tool used to generate random numbers with blocks of 4 is the online software of the Sealedenvelope.com website. Every new patient who is admitted to the intensive care unit, if he meets the inclusion criteria for entering the study, will be placed in one of the A or B groups in the order of arrival and based on the order of randomly generated numbers. For allocation concealment, except for the hospital pharmacist who prepares the drugs for injection and is not present in the study, no one else knows which of the placebo or vitamin D groups referred to each of the A and B groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients (or the patient's family), nurses (care providers), research assistants (who are in charge of data collection) and the statistical analyst will not know about the drug groups (intervention or control) and delivery of medication will be done by a person selected from outside the department (hospital pharmacist).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of AJUMS

Street address

Golestan

City

Ahwaz

Province

Khouzestan

Postal code

6136854578

Approval date

2023-01-17, 1401/10/27

Ethics committee reference number

IR.AJUMS.HGOLESTAN.REC.1401.171

Health conditions studied

1

Description of health condition studied

Acute kidney failure

ICD-10 code

N17

ICD-10 code description

Acute kidney failure

Primary outcomes

1

Description

Creatinin

Timepoint

Before intervention and daily till discharge from ICU (maximum 28 days)

Method of measurement

biochemical auto-analyser

Secondary outcomes

1

Description

Blood urea nitrogen

Timepoint

Before intervention and daily till 28 days or discharge time

Method of measurement

Biochemical auto-analyser

2

Description

Body mass index

Timepoint

Before intervention and 28th day or at discharge time

Method of measurement

Based on the result of dividing weight in kilograms by height in meters

3

Description

Abdominal circumference

Timepoint

Before intervention and 28th day or at discharge time

Method of measurement

Mesurment with a meter

4

Description

Mortality

Timepoint

After 28 days or at discharge time

Method of measurement

Alive or dead

5

Description

Ventilator free days (in first 28 days)

Timepoint

After 28 days or at discharge time

Method of measurement

The number of days of the first 28 days that the patient was not connected to the ventilator

Intervention groups

1

Description

This group will receive an intramuscular dose of placebo (1 milliliter of isotonic NACL 0.9% manufactured by Shahid Ghazi Pharmaceutical company, Tabriz, Iran) during the first 24 hours of hospitalization.

Category

Placebo

2

Description

Intervention group: This group will receive an intramuscular dose of medicine (300,000 units of vitamin D manufactured by Iran's Darupakhsh Pharmaceutical Company) during the first 24 hours of hospitalization.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Dr mohsen savaie

Street address

Golestan hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

mehrnoosh zakerkish

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Grant name

Faculty members grant

Grant code / Reference number

PAIN-0126

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

Yes

Title of funding source

Ahvaz 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
Ahvaz University of Medical Sciences

Full name of responsible person
Mosen savaie

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be 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 data is potentially shareable after de-identifying individuals

When the data will become available and for how long

All data will be available from the publication of the research paper

To whom data/document is available

The data will only be available to researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers can request to receive data for research and clinical uses and to conduct systematic reviews and meta-analyses

From where data/document is obtainable

It is possible to receive data by sending an email (drsavaie@gmail.com)

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

The data will be sent by email no later than one month after the request by academic researchers and scientific centers

Comments

If requested by the journal publishing the article, the data can be uploaded on the journal's website