Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 trumatic 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)

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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 Autoimione 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 mililiter 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
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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 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