

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Activated Vitamin D on treatment of Acute Kidney injury

Protocol summary

Study aim

Evaluation of the therapeutic effect of the active form of vitamin D in the treatment of patients with acute renal failure Renal type

Design

Patients were randomly divided into two groups of 38 using random allocation software. The numbered envelopes will be arranged from 1 to 76, respectively, and within each envelope the type of treatment is specified, which will be implemented after the treatment envelope is opened.

Settings and conduct

This double-blind parallel clinical trial study will be performed on acute renal failure patients referred to the emergency department of Imam Hossein Shahrud Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ages over 18 years, Acute kidney failure according to KDIGO criteria, Having informed consent to participate in the study, Hospitalized in the usual ward, ICU CCU of Imam Hossein Shahrud Hospital, Non-return of creatinine to normal within 48 hours despite fluid replacement or granular and epithelial casts, Ability to eat or own NG Tube, No history of kidney disease and kidney transplant, No history of taking vitamin D compounds for the past 7 days, No active primary parathyroid disease or active granulomatous disease or symptomatic nephrolithiasis in the past 3 months, No pregnancy, no breastfeeding. Exclusion criteria: Administration of cytochrome p450 inhibitors, hemoglobin lower than 7

Intervention groups

The study will be randomly divided into two groups of 38. The case group received 0.25 mg rocanrolol tablets, except for routine renal injury treatment. In the control group, patients will receive no medication other than routine treatment of acute kidney injury.

Main outcome variables

Kidney function The blood urea and creatinine levels are measured

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181010041299N2**

Registration date: **2019-10-31, 1398/08/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-31, 1398/08/09**

Update count: **0**

Registration date

2019-10-31, 1398/08/09

Registrant information

Name

mostafa enayatrad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3239 3961

Email address

mostafaenayatrad@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Activated Vitamin D on treatment of Acute

Kidney injury

Public title

The Effect of Activated Vitamin D on treatment of Acute Kidney injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ages over 18 years Acute kidney failure according to KDIGO criteria Having informed consent to participate in the study Hospitalized in the usual ward, ICU CCU of Imam Hossein Shahrood Hospital Non-return of creatinine to normal within 48 hours despite fluid replacement or granular and epithelial casts Ability to eat or own NG Tube No history of kidney disease and kidney transplant No history of taking vitamin D compounds for the past 7 days No active primary parathyroid disease or active granulomatous disease or symptomatic nephrolithiasis in the past 3 months No pregnancy no breastfeeding

Exclusion criteria:

Get cytochrome p450 inhibitor drugs Hemoglobin less than 7

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly divided into 38 groups using Random allocation software. The numbered envelopes will be arranged in the order of 1 to 76, respectively, and within each envelope the type of treatment is specified, which will be executed after the treatment envelope is opened.

Blinding (investigator's opinion)

Double blinded

Blinding description

To prevent patient awareness and the analyst of the study, each treatment group will be assigned a code that only the specialist program will know about their interpretation. The code commentary will be announced after analyzing the results

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrood University of Medical Sciences

Street address

Room 409. Third floor. medical School. Shahrood University of Medical Sciences. Hafte-Tir Square. Tehran Avenue. Shahrood. Iran

City

Shahrood

Province

Semnan

Postal code

Room 409. Third floor

Approval date

2019-08-17, 1398/05/26

Ethics committee reference number

IR.SHMU.REC.1398.053

Health conditions studied

1

Description of health condition studied

Acute Kidney Failure

ICD-10 code

N17.0

ICD-10 code description

Acute renal failure with tubular necrosis

Primary outcomes

1

Description

Evaluation of kidney function

Timepoint

Daily

Method of measurement

blood test

2

Description

urea

Timepoint

Daily

Method of measurement

blood test

3

Description

creatinine level

Timepoint

Daily

Method of measurement

blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The case group received 0.25 mg rocanrolol tablets, except for routine renal injury treatment.

Category

Treatment - Drugs

2

Description

Control group: patients will receive no medication other than routine treatment of acute kidney injury.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Hospital, Shahroud, Semnan Province

Full name of responsible person

Dr. Asie Emmett Mohammadi

Street address

Imam Hossein Hospital. Imam Hossein Square.
Shahroud. Iran

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3614773947

Phone

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asyomat@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hassan Emamian

Street address

Research Deputy, second floor, medical School,
Shahroud University of Medical Sciences, Hafte-Tir
Square, Tehran Avenue, Shahroud, Iran.

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Grant name

Grant code / Reference number

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

No

Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Asie Emmett Mohammadi

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Monireh Amerian

Position

Supervisor

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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Person responsible for updating data**Contact****Name of organization / entity**

Shahroud University of Medical Sciences

Full name of responsible person

Mostafa Enayatrad

Position

Statistical Advisor

Latest degree

Master

Other areas of specialty/work

Epidemiology

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Email

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

All collected data will be shared after being unidentified and analyzed

When the data will become available and for how long

2020

To whom data/document is available

For all scholars

Under which criteria data/document could be used

For use in studies

From where data/document is obtainable

Supervisor

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

By email and correspondence and justification for use

Comments