

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the efficacy of Calcitriol treatment on acute kidney injury improvement

Protocol summary

Summary

Objectives: evaluating therapeutic effects of active form of vitamin D on acute kidney injury (AKI) improvement. Inclusion criteria: AKI patients aged 18 or more; voluntary participation in the study; admission in ordinary ward, CCU or ICU. exclusion criteria: using vitamin D or its derivatives or having serum Ca level more than 10.5 mg/dl at the beginning of study ; any type of malignancy leading to serum Ca more than 10.5 mg/dl. design: a single blind study (for patients only) on 122 AKI cases in two hospitals who were randomly divided in to two groups including 61 patients each by block A and B method, matched for age, sex, AKI type and severity .setting and conduct and intervention: intervention group patients received 0.25 mg/day calcitriol at the time of AKI diagnosis up to recovery or for three months if recovery did not occur. Control group received placebo as a capsule filled with starch daily since AKI diagnosis up to recovery or for three months if recovery did not happen. BUN and creatinine were checked daily during admission, then weekly for the first month since diagnosis and monthly for 3 months thereafter. after 3 months, recovery time, admission duration, dialysis sessions and maximum creatinine level during admission, frequency of developing chronic kidney disease (CKD) and mortality rate were compared between two groups as primary outcome measures. plasma calcium and phosphorus level were compared at the beginning and at the end of intervention between two groups as secondary outcome measures.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022326716N1**

Registration date: **2016-07-30, 1395/05/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-30, 1395/05/09

Registrant information

Name

Mehrak Montazeran

Name of organization / entity

University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3471 3630

Email address

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2015-03-21, 1394/01/01

Expected recruitment end date

2016-03-20, 1395/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of Calcitriol treatment on acute kidney injury improvement

Public title

Evaluation of the effects of Calcitriol on acute kidney injury

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age:18 years old or more; voluntary participation in the study;.admission in ordinary wards, CCU, ICU Exclusion criteria: Using vitamin D or its derivatives at the time of study initiation;the type of malignancies that lead to calcium level more than 10.5mg/dl;serum calcium level more than 10.5mg/dl

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **122**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committe of Arak University of Medical Sciences

Street address

Arak

City

Arak

Postal code

Approval date

2015-03-11, 1393/12/20

Ethics committee reference number

93-176-29

Health conditions studied

1

Description of health condition studied

acute kidney injury

ICD-10 code

n17.0

ICD-10 code description

acute renal impairment

Primary outcomes

1

Description

maximum creatinin level

Timepoint

daily

Method of measurement

blood sampling

2

Description

number of dialysis sessions during admission

Timepoint

daily

Method of measurement

researcher made checklist

3

Description

admission duration

Timepoint

daily

Method of measurement

researcher made checklist

4

Description

recovery duration

Timepoint

daily

Method of measurement

researcher made checklist

5

Description

becoming CKD

Timepoint

monthly up to three months

Method of measurement

serum creatinin measurement

6

Description

mortality rate

Timepoint

three months maximum

Method of measurement

researcher made checklist

Secondary outcomes

1

Description

hyperphosphatemia

Timepoint

during three months
Method of measurement
blood sampling

2

Description
hypercalcemia
Timepoint
during three months
Method of measurement
blood sampling

Intervention groups

1

Description
0.25 mg of calcitriol was given to the patients in intervention group on a daily basis since AKI diagnosis up to recovery or for 3 months since the diagnosis of AKI if recovery did not happen
Category
Treatment - Drugs

2

Description
One capsule filled with starch was given to the patients in control group on a daily basis since AKI diagnosis up to recovery or for 3 months since the diagnosis of AKI if recovery did not happen
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir Almomnin Hospital
Full name of responsible person
Street address
City
Arak

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research Arak University of Medical Sciences
Full name of responsible person
Dr Mohammad Rafie
Street address
Arak, Sardasht, University of Medical Sciences
City
Arak
Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research Arak University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
ARAK University of Medical Sciences
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Mehrak Montazeran
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty