

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of calcitriol on the incidence of acute rejection among kidney transplant recipients, A pilot, double-blind, randomized placebo-controlled clinical trial

Protocol summary

Study aim

Comparison of the incidence of acute rejection; kidney function based on eGFR; patient survival and allograft survival during the first three months after kidney transplantation between the two groups.

Design

participants are assigned to two intervention and control groups using a four-way block randomization method stratified by donor type and immunological risk.

Settings and conduct

The study is conducted in the kidney transplant department of Imam Khomeini Hospital in Tehran. The drug group receives two 0.25 mcg pearl of Calcitriol daily and the control group received two placebo pearl daily. Participants, health care personnel, data collectors and those who evaluate the outcomes are kept blind to the allocation of study groups. Patients who are vitamin D3 deficient will be treated with vitamin D3 pearl in addition to receiving calcitriol or placebo.

Participants/Inclusion and exclusion criteria

Patients over 18 years of age who are not pregnant or lactating, have a serum calcium level of less than 6 mg/dL and a serum phosphorus level of less than 10.5 mg/dL, are undergoing their first transplant, have no history of desensitization and are not receiving another organ transplant at the same time enter this study. Patients with iPTH less than 50 pg/ml or D3 levels over 100 ng/ml or those not using immunosuppressive regimen are excluded from the study.

Intervention groups

The intervention group will receive calcitriol pearl at a dose of 0.5 micrograms daily and the control group will receive placebo pearl immediately after transplantation along with an immunosuppressive regimen for one month.

Main outcome variables

Investigation of the effectiveness of calcitriol immediately after transplantation on the incidence of

acute rejection cases; allograft function and graft survival in the first trimester after kidney transplantation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260104068546N1**

Registration date: **2026-02-18, 1404/11/29**

Registration timing: **registered_while_recruiting**

Last update: **2026-08-08, 1405/05/17**

Update count: **1**

Registration date

2026-02-18, 1404/11/29

Registrant information

Name

ofogh bigdeli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4466 8709

Email address

ofogh.bigdeli@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-01-21, 1404/11/01

Expected recruitment end date

2027-01-21, 1405/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of calcitriol on the incidence of acute rejection among kidney transplant recipients, A pilot, double-blind, randomized placebo-controlled clinical trial

Public title
Calcitriol in acute kidney transplant rejection

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 living/deceased donor kidney transplant patients in imam khomeini hospital aged over 18 years old serum calcium less than 10.5 mg/dL serum phosphorus less than 6 mg/dL
Exclusion criteria:
 Participate in other interventional clinical studies at the same time retransplantation pregnancy or lactation Simultaneous transplantation of multiple organs Previous intolerance/allergy to vitamin D supplements or calcitriol History of desensitization for transplantation Blood iPTH level less than 50 pg/dL Blood 25 OH-vitamin D3 level over 100 ng/mL Cold ischemia duration more than 4 hours Patient's lack of consent to the study Not receiving defined immunosuppression regimen

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
block

Blinding (investigator's opinion)
Double blinded

Blinding description
participants, principle investigator particularly in investigator initiated trials, healthcare providers, data collectors are blind in this study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Poursina st, 16Azar st, Keshavarz Blvd,Tehran

City

Tehran

Province

Tehran

Postal code

1394971999

Approval date

2026-01-07, 1404/10/17

Ethics committee reference number

IR.TUMS.TIPS.REC.1404.142

Health conditions studied

1

Description of health condition studied

kidney transplantation, acute rejection after kidney transplantation

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

incidence of acute rejection

Timepoint

during first 3 months post kidney transplantation

Method of measurement

kidney biopsy proven or clinical suspicion with clinical cure post corticostroid puls administration.

Secondary outcomes

1

Description

comparison of time of first acute rejection episode between two group

Timepoint

during first 3 months post transplant

Method of measurement

biopsy proven or clinically suspicion which responds to corticostroid puls.

2

Description

comparison of allograft function based on eGFR between

two groups
Timepoint
3 months post transplantation
Method of measurement
measurement of eGFR based on MDRD formula

3

Description
comparison of incidence and kind of infection episodes between two groups
Timepoint
during 3 months post kidney transplantation
Method of measurement
clinical observation and laboratory findings

4

Description
comparison of hospital stay during first hospitalisation post transplantation
Timepoint
during 3 months post kidney transplantation
Method of measurement
hospital documentation

5

Description
comparison of patient survival and graft survival
Timepoint
during 3 months post kidney transplantation
Method of measurement
observation

Intervention groups

1

Description
Intervention group: two pearl of calcitriol 0.25 micrograms per-oral for one month
Category
Prevention

2

Description
Control group: two pearl of placebo per-oral for one month
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Ofogh Bigdeli

Street address
Imam Khomeini Hospital, Baghekhan St, Chamran highway, Tehran, Iran.
City
Tehran
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Tehran
Postal code
1394971999
Phone
+98 21 6119 2085
Email
ofogh.bigdeli@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ofogh Bigdeli
Street address
Imam Khomeini Hospital, Bagherkhan St, Chamran Highway, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1394971999
Phone
+98 21 6119 2085
Email
ofogh.bigdeli@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Ofogh Bigdeli

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

Street address

Kidney transplant department, Imam Khomeini Hospital, Baghekhaneh St, Chamran highway, Tehran, Iran.

City

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Position

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

Tehran University of Medical Sciences

Full name of responsible person

Ofogh Bigdeli

Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

Undecided - It is not yet known if there will be 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