Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 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 impressiveness 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: **2026-02-18, 1404/11/29**
Update count: **0**

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 atfer 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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ofogh Bigdeli

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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
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Kidney transplant department, Imam Khomeini Hospital, Baghekhan St, Chamran highway, Tehran, Iran.
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Person responsible for scientific inquiries

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Resident
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Other areas of specialty/work
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Person responsible for updating data

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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