Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Impact of Once-daily Extended Release Tacrolimus on Intrapatient Variability of Trough Level in Kidney Transplant Recipients

Protocol summary

Study aim
Evaluation of the effect of conversion to extended-release tacrolimus on intrapatient variability of trough level

Design
A singe armed,open Label,non-randomized clinical trial in 100 kidney transplant patients who had IPV on immediate release Tacrolimus

Settings and conduct
A open labeled singla-arm non-randomized clinical trial in kidney transplant patients 1 with Coefficient variation of tacrolimus trough level > 15% will be enrolled in Labbafinejad medical center and their medication will be converted from immediate release to extended release tacrolimus on 1:1 conversion ratio.Coefficient variation of tacrolimus trough level will be calculated during 3 months after conversion.

Participants/Inclusion and exclusion criteria
Kidney transplant patients with coefficient variation of tacrolimus level >15% will be enrolled. Those with history of rejection or non compliance will be excluded

Intervention groups
Transplant patients undergo conversion from immediate release to extended release Tacrolimus

Main outcome variables
Evaluation of coefficient variation of drug level 3 months after conversion

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211221053480N1**
Registration date: **2022-04-10, 1401/01/21**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-10, 1401/01/21**
Update count: **0**

Registration date
2022-04-10, 1401/01/21

Registrant information
Name
Shiva Samavat
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 2360 2188
Email address
samavat@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-04, 1401/01/15

Expected recruitment end date
2022-08-21, 1401/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Impact of Once-daily Extended Release Tacrolimus on Intrapatient Variability of Trough Level in Kidney Transplant Recipients

Public title
Extended Release Tacrolimus on Intrapatient Variability in Kidney Transplant Recipients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:

Kidney transplantation alone At least 6 months post transplantation Stable graft function Stable Tacrolimus dosage Coefficient variation of drug level >30% On tacrolimus twice daily Tacrolimus+MPA+prednisolone regime

Exclusion criteria:

History of acute rejection within 3 months Active infection Not willing to participate Participating in other trials

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Before- After study

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Urology and Nephrology Research Center- Shahid Beheshti University of

Street address

Ministry of health and medical education.South Falamak st. Theran

City

tehran

Province

Tehran

Postal code

141994371

Approval date

2022-01-22, 1400/11/02

Ethics committee reference number

IR.SBMU.UNRC.REC.1400.021

Health conditions studied

1

Description of health condition studied

Kidney transplantation

ICD-10 code

Z94.0

ICD-10 code description

Kidney transplant status

Primary outcomes

1

Description

Coefficient variation of drug level

Timepoint

3 months after conversion

Method of measurement

Drug level measurement with HPLC technique monthly and calculating coefficient variation

Secondary outcomes

1

Description

graft function

Timepoint

3 months after conversion

Method of measurement

GFR with creatinine based formula (CKD-EPI)

Intervention groups

1

Description

Intervention group:In selected patients, convert Prograf®- Astellas to Advagraf®- Astellas : A 1:1 conversion from immediate-release tacrolimus to extended-release tacrolimus capsules and treatment will be continued for at least 3 months.Tacrolimus should be monitored using 24-hour trough (C0) concentrations for the extended-release preparations: in 3 days and monthly for 3 months and coefficient variation will be calculated.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Labbafinejad medical center

Full name of responsible person

Shiva Samavat

Street address

9th Boostan st. Pasadarn Ave.

City

Tehran

Province
Tehran
Postal code
1666663111
Phone
+98 21 2258 0333
Email
shsamavat@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohsen Nafar
Street address
9th Boostan st. Pasadarn Ave.
City
Tehran
Province
Tehran
Postal code
1666663111
Phone
+98 21 2258 0333
Email
m.nafar.md@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Behestan Darou
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Shiva Samavat
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Nephrology
Street address
9th Boostan st. Pasdaran Ave.
City
Tehran
Province
Tehran
Postal code
1666663111
Phone
+98 21 2258 0333
Email
shsamavat@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Shiva Samavat
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Nephrology
Street address
9 th Boostan st. Pasdaran Ave.
City
Tehran
Province
Tehran
Postal code
1666663111
Phone
+98 21 2258 0333
Email
shsamavat@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Shiva Samavat
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Nephrology
Street address
9th Boostan st. Pasdaran Ave.
City
Tehran
Province
Tehran
Postal code
1666663111
Phone

+98 21 2258 0333

Email

shsamavat@gmail.com

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