Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Aug 2026

Comparing de novo versus delayed tacrolimus administration on allograft function in kidney transplant recipients: a randomized, open-label, clinical trial

Protocol summary

Summary

The purpos of the study: Comparing the effects of rapid versus delayed tacrolimus initiation on graft function during the first three months after kidney transplantation. Study design: Randomized, open-label, phase three clinical trial The method of study: a-The study population:Inclusion criteria; all patients ≥ 14 years who will receive first kidney transplantation and they're immunosuppressive regimen regimen contains thymoglobulin induction along with mycophenolate, tacrolimus and prednisolone as maintenance regimen. Exclusion criteria:Patients who have multiple organ transplantation. Sample size: 25 patients in each group. b-Intervention or interventions studied: one group of patients will be administered tacrolimus from a few hours before transplantation at a dose of 0.08 to 0.1 mg / kg / day in two divided doses and continue from the first day after transplantation (with the target level of 8-10 ng / ml) . The second group will start tacrolimus with the same dose from the third day after transplantation. c-Intervention time: First three days after kidney transplantation. d-The primary outcome or consequences studied: -Dialy evaluation of serum creatinine and urine output and required dialysis during hospitalization. -Comparing the incidence and duration of DGF and ATN during hospitalization -Comparing the incidence of acute rejection within the first 3 months after transplantation -Compare the serum creatinine concentrations at the discharge time -Compare rates of graft survival within first 3 months after transplantation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201604253043N11**

Registration date: **2016-05-21, 1395/03/01**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-21, 1395/03/01

Registrant information

Name

Simin Dashti-Khavidaki

Name of organization / entity

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Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Governmental (Tehran University of Medical Sciences)

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2017-09-21, 1396/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing de novo versus delayed tacrolimus administration on allograft function in kidney transplant recipients: a randomized, open-label, clinical trial

Public title
Comparing the starting time of tacrolimus administration in management of kidney transplant recipients
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: All patients who underwent the first of Deceased donor or Living donor kidney transplantation in Imam Khomeini Hospital Complex, Tehran, Iran ; Age is ≥ 14 y ; Patients who receive thymoglobulin induction ; Patients who receive Mycophenolate and Prednisone plus Tacrolimus as immunosuppressive regimen. Exclusion criteria: Patients with unstable cardiac, hepatic, pulmonary functions after kidney transplantation ; Patients who have multiple organ transplantation ; Patients with known malignancy.
Age
From **14 years** old to **75 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences, 16 Azar St., Enghelab St, Tehran, Iran.
City
Tehran
Postal code
Approval date
2016-05-09, 1395/02/20
Ethics committee reference number
IR.TUMS.REC.1395.2575

Health conditions studied

1

Description of health condition studied
Kidney transplant
ICD-10 code
Z94.0
ICD-10 code description
Kidney transplant status

Primary outcomes

1

Description
Recipient's serum creatinine
Timepoint
Before the transplantation, every 6 hours on the first day of transplant, then daily during hospitalization, then weekly until the end of the first month after transplant, then monthly until the end of the third month after transplat
Method of measurement
Blood samples in laboratories in milligrams / deciliter

2

Description
Recipient's urine output
Timepoint
Before transplantation and daily during hospitalization
Method of measurement
Graduated container in ml/day

3

Description
Incidence of DGF
Timepoint
During first week after transplantation
Method of measurement
Need for dialysis

Secondary outcomes

1

Description
Graft survival
Timepoint
First three months after transplantation
Method of measurement
Number of functioning kidney

2

Description
The incidence of acute rejection
Timepoint
During the first three months after transplantation
Method of measurement

Based on function of transplanted kidney

Intervention groups

1

Description
Intervention 1: Tacrolimus will be started from a few hours before transplantation at a dose of 0.08 to 0.1 mg / kg / day in two divided doses (The target level of 8-10 ng / ml). Serum creatinine and urine output will be assessed daily during hospitalization. Serum creatinine witll be assessed monthly after hospital discharge up to month 3 after kidney transplantatioↄ. Tacrolimus whole blood concentrations will be checked twice weekly during hospitalizations and monthly thereafter up to month 3 after transplantation.

Category
Prevention

2

Description
Intervention 2:Tacrolimus will be started from the third day after kidney transplantation at a dose of 0.08 to 0.1 mg / kg / day in two divided doses (The target level of 8-10 ng / ml). Serum creatinine and urine output will be assessed daily during hospitalization. Serum creatinine witll be assessed monthly after hospital discharge up to month 3 after kidney transplantation. Tacrolimus whole blood concentrations will be checked twice weekly during hospitalizations and monthly thereafter up to month 3 after transplantation.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Kidney transplant ward, Imam Khomeini Hospital Complex

Full name of responsible person
Dr Maryam Ghadimi

Street address

City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Masoud Younesian

Street address
16 Azar St., Faculty of Pharmacy, Tehran University of Medical Sciences

City
Tehran

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
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
Department of Clinical Pharmacy, Tehran University of Medical Sciences

Full name of responsible person
Dr Maryam Ghadimi

Position
Resident of Clinical Pharmacy

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Dr. Simin Dashti-Khavidaki

Position
Professor of Clinical Pharmacy

Other areas of specialty/work

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Full name of responsible person

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City

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