

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 purpose 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 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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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 \geq 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 transplant

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 will 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

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 will 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

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Resident of Clinical Pharmacy

Other areas of specialty/work

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Person responsible for scientific inquiries

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Other areas of specialty/work

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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