

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of two different drug regimen containing tacrolimus and cyclosporine on graft survival and the survival rate of patients as immunosuppressive regimens in kidney transplantation

Protocol summary

Summary

This study compare the effect of two drug regimen containing tacrolimus and cyclosporine on graft survival and the survival rate of patients as immunosuppressive regimens in kidney transplantation, in the center of Imam Reza (AS), Kermanshah, Iran. We will recruit 100 patients in each group. Inclusion criteria: all patients with chronic renal failure aged 16 to 65 who were undergoing kidney transplantation and immunosuppressive therapy for graft. Exclusion criteria: patients with other diseases such as cancer; intraoperative surgical complications in renal transplantation in grafts; graft loss due to vascular complications created from the graft surgery; death (due to other causes than rejection); switching immunosuppressive treatment regimen for any reason. Patients will be divided into two groups under two drug regimens: The first diet includes tacrolimus + micofenolate meftile «Cellcept» + prednisolone and second regime includes cyclosporine + micofenolate meftile «Cellcept» + prednisone. For one year, both groups will be under the detailed follow up and review of acute rejection, chronic rejection, measurement of plasma creatinine levels and creatinine clearance rate, graft and patient survival factors. Patients in the months of third, sixth, ninth and twelfth after transplantation will be visited and variables will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105166500N1**

Registration date: **2011-06-19, 1390/03/29**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-06-19, 1390/03/29

Registrant information

Name

Abdoreza Mahrui

Name of organization / entity

Kermanshah University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 6301

Email address

abmahrooei@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah university of medical sciences

Expected recruitment start date

2011-05-03, 1390/02/13

Expected recruitment end date

2013-01-02, 1391/10/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two different drug regimen containing tacrolimus and cyclosporine on graft survival and the survival rate of patients as immunosuppressive regimens in kidney transplantation

Public title

Comparison of cyclosporine and tacrolimus in two

immunosuppressive drug regimen in patients undergoing kidney transplantation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: all patients with chronic renal failure aged 16 to 65 who were undergoing kidney transplantation and immunosuppressive therapy for graft. Exclusion criteria: patients with other diseases such as cancer; intraoperative surgical complications in renal transplantation in grafts; graft loss due to vascular complications created from the graft surgery; death (due to other causes than rejection); switching immunosuppressive treatment regimen for any reason.

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **200**

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

Kermanshah university of medical sciences

Street address

building no 2 of Kermenshah university of medical sciences, Shahid Beheshti Blvrd

City

Kermanshah

Postal code

Approval date

2011-05-03, 1390/02/13

Ethics committee reference number

420

Health conditions studied

1

Description of health condition studied

survival of transplanted kidney

ICD-10 code

T86.1

ICD-10 code description

Kidney transplant failure and rejection

Primary outcomes

1

Description

acute rejection of kidney transplantation

Timepoint

1 , 3 , 6 , 9 , 12 months after transplantation

Method of measurement

clinical findings, sonographic findings, findings of DTPA scan, biopsy

2

Description

coronic rejection of kidney transplantation

Timepoint

1 , 3 , 6 , 9 , 12 months after transplantation

Method of measurement

Gradual increase in plasma creatinine and the need for dialysis in patient that has not required dialysis. based on clinical symptoms, renal biopsy diagnosed increase of creatinine gradually.

Secondary outcomes

1

Description

GFR

Timepoint

1 , 3 , 6 , 9 , 12 months after transplantation

Method of measurement

with GFR formula

2

Description

drugs side effect

Timepoint

1 , 3 , 6 , 9 , 12 months after transplantation

Method of measurement

alergy, intolerance, blood presure increase

Intervention groups

1

Description

Group B: tacrolimus: 1 mg twice a day immediately after transplantation until a year. Micofenolate meftile: the night before the transplant, 1 g, twice a day until a year. Prednisolone: at first, 3 pulse methylprednisolone for 3

days after transplantation is given, then 1 mg/kg/day gradually to 2 / 0 mg/kg/day and reduction is given in one year to 10 mg/day.

Category

Treatment - Drugs

2

Description

Group A: Cyclosporine: after transplantation, 12 mg/kg/day, gradually reduced to half the dose in the first month and then a dose of 5 mgr/kg/day, until one year. Micofenolate meftile: the night before the transplant, 1 g, twice a day until a year. Prednisolone: at first, 3 pulse methylprednisolone for 3 days after transplantation is given, then 1 mg/kg/day gradually to 2 / 0 mg/kg/day and reduction is given in one year to 10 mg/day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza hospital

Full name of responsible person

Street address

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences and Health Services

Full name of responsible person

Dr. Farid Najafi

Street address

Bulding No2 of Kermanshah University of Medical Sciences and Health Services, Shahid Beheshti Blvrd.

City

Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kermanshah University of Medical Sciences and Health Services

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

Kermanshah University of Medical Sciences and Health Services

Full name of responsible person

Dr. Abdoreza Mahrui

Position

Resident of internal medicine

Other areas of specialty/work

Street address

Internal medicine Department of Imam Reza Hospital

City

Kermanshah

Postal code

Phone

+98 83 1427 6301

Fax

Email

abmahrooei@kums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences and Health Services

Full name of responsible person

D. Dariush Daisi

Position

Specialist in Nephrology

Other areas of specialty/work

Street address

Internal medicine Department of Imam Reza Hospital

City

Kermanshah

Postal code

Phone

+98 83 1427 6301

Fax

+98 83 1427 6477

Email

abmahrooei@kums.ac.ir

Web page address

Person responsible for updating data

Contact

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