Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of the effectiveness of De novo immunosuppressive regimen of sirolimus plus tacrolimus versus tacrolimus plus Mycofenolic acid in renal transplant recipients

Protocol summary

Study aim
Comparison the efficacy of sirolimus use in combination with tacrolimus as a De novo immunosuppressive regimen with the regimen contains tacrolimus and mycophenolic acid in kidney transplant recipients

Design
A randomized controlled trial with parallel group design. Randomization will computer generated. Block randomization method will be used and each block was of 10 patients

Settings and conduct
kidney transplant recipients between years 2016 and 2017 in Shahid Labbafinejad Medical center will enrolle for the study.

Participants/Inclusion and exclusion criteria
Patients who received kidney transplant from cadaver or living unrelated donor (age of cadaveric donor < 50 years) that were negative for panel reactive antibody (cytotoxicity), pre-transplantation anti-HLA, will be recruited. All patient were 18 to 65 years of age and had body mass index (BMI) less than 30 kg/m2. Patients who received kidney transplant previously will not include.

Intervention groups
In test group, sirolimus, 2 mg as a loading dose followed by doses to reach the trough levels of 3-5 ng/mL as maintenance regimen in combination with tacrolimus, 0.08 mg/kg/day for trough levels of 6-7 ng/mL in first 6 months after transplantation will be administered. In control group, tacrolimus, 0.1 mg/kg/day to reach the trough level of 8-10 ng/ml; mycophenolate sodium, 1080 mg daily for 7 first day followed by 720 mg as maintenance regimen in first 6 months after transplant will be administered

Main outcome variables
Renal function, graft rejection

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160412027346N6**
Registration date: **2019-04-30, 1398/02/10**
Registration timing: **retrospective**

Last update: **2019-04-30, 1398/02/10**
Update count: **0**

Registration date
2019-04-30, 1398/02/10

Registrant information

Name
Shadi Ziaie

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 8887 3704

Email address
shadiziaie@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2016-01-20, 1394/10/30

Expected recruitment end date
2017-12-21, 1396/09/30

Actual recruitment start date
2016-02-23, 1394/12/04

Actual recruitment end date
2017-12-25, 1396/10/04

Trial completion date

2017-12-30, 1396/10/09

Scientific title
Comparison of the effectiveness of De novo immunosuppressive regimen of sirolimus plus tacrolimus versus tacrolimus plus Mycofenolic acid in renal transplant recipients

Public title
Efficacy of two type of immunosuppressive regimen in rate of graft rejection in the kidney transplant recipients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who received kidney transplant from cadaver Patients who received kidney transplant from unrelated living donor (age of cadaveric donor > 50 years) Negative for panel reactive antibody Negative for pre-transplantation anti-HLA BMI less than 30 kg/m2 Age between 18 to 65 years

Exclusion criteria:
previously transplanted patients

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **46**
Actual sample size reached: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
The random allocation sequence will computer generate and consist of series of group number (either 1 = A or 2 = B) for each consecutive patient. Block randomization method will use and each block will be consist of 10 patients. Each block includes 5 patients who will receive sirolimus plus tacrolimus and 5 patients who will receive tacrolimus plus mycophenolate.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name
BioMed Central Ltd

Secondary trial Id
ISRCTN19991928

Registration date
2637-11-06, 2016/08/15

Ethics committees

1

Ethics committee

Name of ethics committee
ethics committee of Shahid Beheshti University of Medical Sciences

Street address
Tehran Province, Tehran, Velenjak, Arabi Ave

City
Tehran

Province
Tehran

Postal code
19839-63113

Approval date
2016-08-15, 1395/05/25

Ethics committee reference number
IR.SBMU.UNRC.1394.25

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
Estimation of glomerular filtration rate

Timepoint
at baseline and months 3, 6 and 12

Method of measurement
based on Modification of Diet in Renal Disease (MDRD)

2

Description
Biopsy proven acute rejection

Timepoint
months 3 and 12

Method of measurement
based on biopsy and screening renal tissue

Secondary outcomes

1

Description
Incidence of borderline changes, subclinical acute cellular rejection and subclinical antibody mediated

rejection

Timepoint

month 4

Method of measurement

measured by protocol biopsy

2

Description

Incidence of new-onset diabetes after transplantation

Timepoint

at 3, 6, 12 months

Method of measurement

measurement of blood glucose

3

Description

Incidence of donor specific anti-HLA antibodies

Timepoint

at 4 and 12 months

Method of measurement

measured using solid phase ELISA

4

Description

Incidence of hypertension

Timepoint

3, 6 and 12 months

Method of measurement

by using mercury sphygmomanometer

5

Description

Incidence of dyslipidemia

Timepoint

at months 3, 6 and 12

Method of measurement

total cholesterol, LDL-C, HDL-C and TG serum level

6

Description

Incidence of CMV viremia (>2000 copies/ml) and CMV disease (fever, leukopenia or organ involvement with CMV DNAemia >2000 copies/ml)

Timepoint

every month for first 3 months and then every 3 months for 1 year

Method of measurement

measured using CMV viral load By PCR

7

Description

Incidence of BK viremia (>10000 copy/ml blood) and BK associated nephropathy

Timepoint

every month for first 3 months then every 3 months

Method of measurement

measured using BK virus plasma PCR

Intervention groups

1

Description

Intervention group: Immunosuppressive medications will be administered with the following dosages for patients after enrollment: ATG 3 mg/kg divided in 3 to 4 doses daily. Methylprednisolone 250 mg daily for 2 days, followed by prednisolone 1 mg/kg (maximum of 60 mg) for 3 days afterward, then it will taper down by 5 mg daily to reach the dose of 15 mg on day 14, 10 mg daily on day 30 and finally 5 mg daily on day 60 and thereafter. afterward, SRL, 2 mg as a loading dose followed by doses to reach the trough levels of 3-5 ng/mL as maintenance regimen in combination with TAC, 0.08 mg/kg/day for trough levels of 6-7 ng/mL in first 6 months after transplantation will be administered

Category

Treatment - Drugs

2

Description

Control group: Immunosuppressive medications will be administered with the following dosages for patients after enrollment: ATG 3 mg/kg divided in 3 to 4 daily doses , Methylprednisolone 250 mg daily for 2 days, followed by prednisolone 1 mg/kg (maximum of 60 mg) for 3 days afterward, then prednisolone will be tapered by 5 mg daily to reach the dose of 15 mg on day 14, 10 mg daily on day 30 and finally 5 mg daily on day 60 and thereafter. Afterward, TAC, 0.1 mg/kg/day to reach the trough level of 8-12 ng/ml; Myfortic®, 1080 mg daily for 7 first day followed by 720 mg as maintenance regimen in first 6 months after transplant will be administered.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Labbafinejad Medical center

Full name of responsible person

Dr Shadi Ziaie

Street address

9th Boostan Pasdaran St Tehran

City

Tehran

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Postal code

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Shadiziaie@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Shadi Ziaie
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Shadi Ziaie
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

Contact
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Full name of responsible person
Omid moradi
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Clinical pharmacy resident
Latest degree
Medical doctor
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O_moradi@sbmu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

at the end of the study all the data after blinding and statistical analysis based on what mentioned in methodology will be extracted and published online as a scientific paper

When the data will become available and for how long

6 months after publishing the results

To whom data/document is available

responsible investigator, Physicians, academician investigators

Under which criteria data/document could be used

only with permission of responsible investigator or regulatories

From where data/document is obtainable

Responsible investigator

What processes are involved for a request to access data/document

Through contacting with responsible investigator

Comments