Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing plasmapheresis+IVIg vs plasmapheresis+IVIg+ High dose rituximab vs plasmapheresis+IVIg+ Low dose rituximab on the management of antibody-mediated rejection in kidney transplant recipients

Protocol summary

Summary

The aim of the study: Recognizing the best treatment regimen to reach better graft survival, lower adverse effects and lower cost based on the medications which are existed in Iran's pharmacopea. Study design: Non-randomized, non-parallel group, open-label clinical study. a- The study population: Inclusion criteria: Kidney transplant recipients underwent immunosuppresion regimen consists of Tacrolimus, Mycophenolate and Prednisolone who are clinically suspicious or definitely diagnosed with AMR (Antibody-mediated acute rejection). Sample size: 10 patients in each group. b- Interventions: Patients will receive treatment regimens including plasmapheresis and IVIg or the plasmapheresis plus IVIg plus 4 weekly doses of 375mg/m2 Rituximab or plasmapheresis plus IVIg plus 2 weekly doses of 375mg/m2 Rituximab. The first two regimens are the regimens currently being used in our transplantation centers. The third group is the group will undergo the intervention. c- Time of intervention: When the patient is clinically suspicious or definitely diagnosed with AMR. d- The outcomes studied: Clinical condition of the patients, serum creatinine, urine output, complete blood count and serum LDH (Lactate dehydrogenase) will be compared on a daily basis during hospitalization and then monthly to the end of 3-month follow-up period among 3 groups. Patient and graft survival will be compared as a secondary outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201508103043N10**
Registration date: **2016-08-17, 1395/05/27**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-08-17, 1395/05/27

Registrant information

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Simin Dashti-Khavidaki
Name of organization / entity
Tehran University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2017-02-19, 1395/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing plasmapheresis+IVIg vs plasmapheresis+IVIg+ High dose rituximab vs plasmapheresis+IVIg+ Low dose rituximab on the management of antibody-mediated rejection in kidney transplant recipients

Public title
Comparing high dose and low dose Rituximab in the treatment of rejection in kidney transplant recipients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: 1. Kidney transplant recipients recieve immunosuppression regimen including Thymoglobulin+Tacrolimus+Mycophenolate+ Prednisolone 2. Strong clinical suspicious of antibody-mediated acute rejection (AMR) (sudden impairment in function of the graft including anuria and increasing serum creatinine after a few days of having functional kidney) or definite diagnosis of AMR (morphologic and immunopathologic evidences of AMR in a biopsy specimen of the graft) or measuring serum DSA (Donor-specific antibody) levels. Exclusion criteria: 1. The patient's preference not to proceed the treatment 2. Evidence of definite diagnosis other than AMR in Pathologic report 3. Serious side effects associated to the medications used in this trial
Age
From **14 years** old to **75 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

1

Registry name
-
Secondary trial Id
-
Registration date
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
2016-02-23, 1394/12/04
Ethics committee reference number
IR.TUMS.REC.1394.2059

Health conditions studied

1

Description of health condition studied
Antibody-mediated rejection in kidney transplant recipients
ICD-10 code
Z94.0
ICD-10 code description
Kidney transplant status

Primary outcomes

1

Description
Recipient serum Creatinine
Timepoint
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 (jaffe technique)

2

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

Secondary outcomes

1

Description
Complete blood count
Timepoint
Daily during hospitalization
Method of measurement
Laboratory

2

Description
Srum lactate dehydrogenase
Timepoint

Twice weekly during hospitalization

Method of measurement

Laboratory

3

Description

3-month Graft survival

Timepoint

Monthly follow-up

Method of measurement

Going back of recipient to dialysis

4

Description

3-month patient survival

Timepoint

Monthly follow-up

Method of measurement

Patient death or live

Intervention groups

1

Description

Control group (regimen currently being used in some Iranian transplant centers): Plasmapheresis+ IVIg+ high-dose Rituximab: Patients will receive 100mg/kg Of IVIg after each plasmapheresis session. 4 doses of Rituximab (375mg/m2) will be administered on weekly basis. The next plasmapheresis session after administration of Rituximab will be 48-72 hours later.

Category

Treatment - Drugs

2

Description

Intervention group: Plasmapheresis+ IVIg+ low-dose Rituximab: IVIg (100mg/kg) will be infused after each plasmaoheresis session.2 doses of Rituximab (375mg/m2) will be administered on a weekly basis. The next plasmapheresis session after Rituximab administration will be 48-72 hours later

Category

Treatment - Drugs

3

Description

Control group (regimen currently being used in some Iranian transplant centers): IVIg+ plasmapheresis. The patients will receive 300-400mg/kg of IVIg after each plasmapheresis session to the total cumulative dose of 2g/kg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kidney transplant ward, Imam Khomeini Hospital Complex

Full name of responsible person

Fatemeh Ahmadi

Street address

City

Tehran

2

Recruitment center

Name of recruitment center

Kidney transplant ward, Milad Hospital

Full name of responsible person

Fatemeh Ahmadi

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

Fatemeh Ahmadi

Position

Resident of Clinical Pharmacy

Other areas of specialty/work

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Person responsible for scientific inquiries

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Dr. Simin Dashti-Khavidaki

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Professor of Clinical Pharmacy

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