Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the therapeutic effect of the combination of IVIG and leflunomide compared to treatment with IVIG alone in patients with kidney transplant rejection due to BK virus.

Protocol summary

Study aim
Comparison of the combination of immunoglubulin (IVIG) and leflunomide with IVIG in patients with BK virus infection in kidney transplant patients
Design
A randomized controlled clinical trial on 30 people
Settings and conduct
Shiraz Organ Transplantation Hospital - monthly blood sampling to check creatinine and virus level
Participants/Inclusion and exclusion criteria
1. The experience of the first kidney transplant 2. Age of patients over 18 years 3. Lack of relationship between CKD patients and autoimmune diseases
Intervention groups
The combination of IVIG and leflunomide compared to IVIG in patients with BK virus infection in kidney transplant patients
Main outcome variables
BK viral load level

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230214057417N1**
Registration date: **2023-11-23, 1402/09/02**
Registration timing: **retrospective**

Last update: **2023-11-23, 1402/09/02**
Update count: **0**
Registration date
2023-11-23, 1402/09/02

Registrant information
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Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-02-15, 1399/11/27
Expected recruitment end date
2023-10-22, 1402/07/30
Actual recruitment start date
2021-02-15, 1399/11/27
Actual recruitment end date
2023-10-22, 1402/07/30
Trial completion date
2023-10-22, 1402/07/30

Scientific title
Comparison of the therapeutic effect of the combination of IVIG and leflunomide compared to treatment with IVIG alone in patients with kidney transplant rejection due to BK virus.

Public title
• Comparison of graft loss rate in patients receiving ivig drug with patients receiving ivig and leflunomide regimen.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
They were transplanted for the first time, and the age of the patients is over 18 years old, and the CKD patients were not in the field of autoimmune diseases.

Exclusion criteria:
Autoimmune diseases - Any drug side effects - Having a history of treatment due to BK VIRUS

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **30**
Actual sample size reached: **15**

Randomization (investigator's opinion)
Randomized

Randomization description
kidney transplant patients with BK virus infection who meet the inclusion criteria will randomly allocated into 2 groups.Block permutation randomization will be used to assign groups. Patients participating in the research will be divided into two groups using blocks of 4 using the letters A and B (for the equality of the groups).One group will receive IVIG , and the other group will receive IVIG + leflunomide. For block permutation randomization, the sealed envelope method will be used with a random sequence.

Blinding (investigator's opinion)
Double blinded

Blinding description
Blinding is in a way that the participant does not know the type of actions that will be done for him; Also, the person analyzing does not know the action that is done in each group. But since the parameters are measured by the researcher, there will be no blinding.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
raja 8 , rajaee blvd

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yasoyj

Province
Kohgilouyeh-va-Boyrahmad

Postal code
7591968168

Approval date
2021-01-20, 1399/11/01

Ethics committee reference number
21031

Health conditions studied

1

Description of health condition studied
patients with BK virus infection in kidney transplant patients

ICD-10 code
T86.13

ICD-10 code description
Kidney transplant infectio

Primary outcomes

1

Description
It is a leading interventional research, and the patients studied were under transplant for the first time, and the patients were over 18 years old, and the CKD patients did not have autoimmune diseases, and at any time of the study, if the patients had an increase in the serum creatinine level, samples were taken. Kidneys are done and if any type of transplant rejection is reported, they will be excluded from the study. Patients will be excluded from the study if they have any side effects of medication, and if they have a history of treatment due to BK VIRUS, which of course did not happen in our study. and the serum BK VIRUS level was checked monthly by PCR method and the result was recorded.The implementation method was to randomly divide the patients into two groups, one group received IVIG and the other group received leflunomide in addition to IVIG. For all patients, IVIG made by Biotest in England, which contains 5 grams of immunoglobulin in 100 cc vials, with a dose of 300 mg/kg every 3 weeks for three doses, and for people who, in addition to IVIG, leflunomide, made by Erna Hayat Danesh, in the form of 20 tablets There are milligrams, in the first 5 days, 100 mg orally was prescribed and from the sixth day onwards, 40 mg orally was prescribed daily for three months. Before IVIG injection, 500 cc of normal saline was prescribed to the patients for hydration. The patients who received leflunamide stopped taking mycophenolate mofetil, and the dose of mycophenolate mofetil was halved for those who received only IVIG.Patients who were taking tacrolimus and cyclosporine continued to take these two drugs with the previous routine. Meanwhile, in case of taking these two drugs - cyclosporine and tacrolimus - during the study, the serum level of the drugs was measured monthly and the serum level of tacrolimus was 4-6 ng/ml and the serum level of cyclosporine was maintained at 10-60 ng/ml. At the end of the study, the

results of the two mentioned groups were measured and compared in terms of serum levels, BK VIRUS, serum creatinine and graft loss.

Timepoint

The length of the treatment and study period of the patients is two months, and the serum BK VIRUS level was checked monthly by PCR method and the results were recorded.

Method of measurement

It is a leading interventional research, and the patients studied were under transplant for the first time, and the patients were over 18 years old, and the CKD patients did not have autoimmune diseases, and at any time of the study, if the patients had an increase in the serum creatinine level, samples were taken. Kidneys are done and if any type of transplant rejection is reported, they will be excluded from the study. Patients will be excluded from the study if they have any drug side effects, and they will also be excluded from the study if they have a history of treatment due to BK VIRUS, which of course did not happen in our study.

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In the present study, kidney transplant patients with BK virus infection were randomly divided into two groups. One group received IVIG and the other group received leflunomide in addition to IVIG. Before IVIG injection, 500 cc of normal saline was administered to all patients for hydration. IVG drug (Biotest company of England) is available in 100 cc vials containing 5 grams of immunoglobulin. In the first group, IVG drug was injected with a dose of 300 mg/kg once every 3 weeks (for three times).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

namazi hospital

Full name of responsible person

pedram abdizadeh

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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

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

No

Title of funding source

Shiraz Renal Research Center

Proportion provided by this source

70

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

Shiraz University of Medical Sciences

Full name of responsible person

pedram abdizadeh

Position

Internal medicine specialist

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
No - There is not a plan to make this available