Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

Study of the efficiency of a novel desensitization protocol based on platelet infusion for decreasing anti-HLA antibody titer and increasing transplant ability

Protocol summary

Study aim

1. Study of the CPRA change and increasing the chance of finding a compatible donor before and after the implementation of a new desensitization protocol based on platelet infusion in kidney transplantation in patients with anti HLA antibodies 2. Study of the change of MFI before and after the implementation of the new desensitization protocol based on platelet infusion in kidney transplantation in patients with anti HLA antibodies 3. Determining the side effects of receiving platelets (such as infection, thrombosis, etc.) in kidney transplantation in patients with anti HLA antibodies 4. Determining the side effects of receiving BORTEZOMIB in kidney transplantation in patients with anti HLA ab

Design

Clinical trial for available patient, single group, unblinded, phase 1-2 for approximately 45 patients

Settings and conduct

This study will include patients who need kidney transplantation with a living donor but have been previously sensitized and finding a compatible donor for them is difficult. Anti HLA antibodies are risk factors for rejection and allograft loss. If the patient has a positive CDC test or a history of sensitization (like multiple transplants), tests such as flow cytometry panel, LUMINEX، CPRA will be performed according to a special rule . If the CPRA is more than 95%, our patient needs desensitization .

Participants/Inclusion and exclusion criteria

Being over 18 years old and under 70 years old , No current infectious or neoplastic disease , and having favorable results on cardiac examination in the last three months, Patients with CPRA greater than 95%.

Intervention groups

In the intervention(new desensitization protocol) group patients receive rituximab, platelets, bortezomib, IVIG, cotrimoxazole, pantoprazole, vancomycin, tacrolimus, and prednisolone.

Main outcome variables

Reducing CPRA or reducing MFI

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221101056360N1**
Registration date: **2023-01-30, 1401/11/10**
Registration timing: **registered_while_recruiting**

Last update: **2023-01-30, 1401/11/10**
Update count: **0**

Registration date

2023-01-30, 1401/11/10

Registrant information

Name

Behzad Einollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8755 9726

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-20, 1401/02/30

Expected recruitment end date

2023-07-23, 1402/05/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study of the efficiency of a novel desensitization protocol based on platelet infusion for decreasing anti-HLA antibody titer and increasing transplant ability

Public title
Study of the efficiency of a novel desensitization protocol based on platelet infusion for decreasing anti-HLA antibody titer and increasing transplant ability
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Being over 18 years old and under 70 years old No current infectious or neoplastic disease Having favorable results on cardiac examination in the last three months Patients with CPRA greater than 95%
Exclusion criteria:
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research ethics committee of Baqiyatallah University of Medical Sciences
Street address
MollaSadra street , Vanak Square , Tehran
City
Tehran
Province
Tehran
Postal code
1435916471
Approval date
2022-05-18, 1401/02/28
Ethics committee reference number
IR.BMSU.REC.1401.061

Health conditions studied

1

Description of health condition studied
Novel desensitization protocol based on platelet, Anti-HLA antibody ,Kidney transplant, Desensitization
ICD-10 code
Z94.0
ICD-10 code description
Kidney transplant

Primary outcomes

1

Description
CPRA: The CPRA estimates the percentage of donors with whom a particular recipient would be incompatible . If CPRA is more than 95%, our patient needs desensitization.
Timepoint
Before desensitization, two months after desensitization
Method of measurement
Lab test : Calculated panel reactive antibody

Secondary outcomes

1

Description
The amount of antibodies against HLAI and HLAII subunits as mean fluorescent intensity (MFI) in the LUMINEX method
Timepoint
Before desensitization, two months after desensitization
Method of measurement
Mean Fluorescence Intensity Donor-Specific Anti-HLA Antibodies on LUMINEX platform (lab test)

Intervention groups

1

Description
Intervention group: In this group of patients ,the following interventions are made .Each patient prophylaxis regimen includes cotrimoxazole 480 OD, pantoprazole 40 OD, vancomycin 500 after each platelet infusion. The immunosuppressive drugs that are used include PROGRAF 1 mg BD, prednisolone 10 mg OD. we give a single dose of Rituximab 500 mg on the first day of desensitization . After 3 days, 1: Platelet loading dose:

10 units of random platelets or two bags of single donor platelets, which continues for two days. 2: After the second day, platelets infusion continues (3 to 5 units of random platelets every other day) 3:BORTEZOMIB with the dosage of 1.3mg/m2 will be started for the patient every other day for 4 days 4: After completing four doses of BORTEZOMIB, the next four doses are continued as one dose every 72 hours. Also, in addition to receiving the above drugs, the patient receives IVIG at a dose of 1-2 gr/kg for three to five days. After two months, LUMINEX class one and two will be rechecked and immunosuppressive drugs are continued until the transplantation.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Baqiyatallah Hospital
Full name of responsible person
Behzad Einollahi
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Email
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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
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Behzad einollahi
Position
Professor
Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available