

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)

Phone

+98 21 8755 9726

Email address

einollahib@bmsu.ac.ir

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

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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**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

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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

Subspecialist

Other areas of specialty/work

Nephrology

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Position

Non-academic general practitioner

Latest degree

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Other areas of specialty/work

General Practitioner

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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