# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 2026

## Compare changes two subsets of regulatory T cells (Treg) and gene expression of Foxp3, RORγT, T-bet and GATA-3 in kidney transplant patients under two different treatment protocols

## Protocol summary

**Summary**

Of the 20 patients (two groups of 10 patients each with a different drug protocols) that for various reasons are transplant candidates According to standard protocols under immunosuppressive therapy after transplantation.10 cc of blood from patients before and 4 months after transplantation is taken(In case of rejection of allograft we will measure the biomarkers ). in addition, a list containing demographic, clinical, pharmacology and laboratory for each patient completed.In all samples after purification of mRNA and synthesis of c DNA, gene expression of Foxp3, RORγT, T-bet, and GATA-3 are examined with Real-time PCR technique.The frequency of CD4 + CD25 + FOXP3 + Treg cells and CD8 + CD28- Treg are analyzed by flow cytometry.then we use a statistical method to analysis the correlation between new data and clinical and paraclinical findings.The sensitivity and specificity of biomarkers for the detection of transplant rejection will be checked.so, The aim of this study is the effective treatment to prevent rejection and if we see a significant correlation between the frequency of these cells and the incidence of acute rejection or chronic allograft and clinical findings, we can prophesy the kidney transplant status with such biomarkers measuring instead of using invasive methods

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2016062528620N1**
Registration date: **2017-01-20, 1395/11/01**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

**Registration date**

2017-01-20, 1395/11/01

**Registrant information**

**Name**
saeedeh jamali
**Name of organization / entity**
Tehran University of Medical Sciences
**Country**
Iran (Islamic Republic of)
**Phone**
+98 21 6695 3009
**Email address**
sjamali@razi.tums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Molecular Immunology Research Center, Behestan Drug Administration, Tehran University of Medical Sciences

**Expected recruitment start date**

2016-06-04, 1395/03/15

**Expected recruitment end date**

2017-06-05, 1396/03/15

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Compare changes two subsets of regulatory T cells (Treg) and gene expression of Foxp3, RORγT, T-bet and GATA-3 in kidney transplant patients under two different treatment protocols

**Public title**

The effect of two different drug protocols on the kidney transplant patients immune system

**Purpose**
Prevention
**Inclusion/Exclusion criteria**
Inclusion criteria: 1.Patients who receive a transplant for the first time; 2.live or unrelated cadavric donor (under 50 years); 3.All transplant recipients in terms of PRA (Panel reactive antibody) are negative; 4. Patients anti HLA antibody should be negative; 5. BMI <30; 6.Transplant recipients age: 65-18 years old; 7. The possibility of underlying diseases and infections in patients is low. Exclusion criteria: 1. If the patient does not want to cooperate in the study; 2. Patients suffering from the nephrotoxicity.
**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: **20**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Tehran University of Medical Sciences
**Street address**
Tehran University of Medical Sciences, Qhods St., Keshavarz blvd.
**City**
Tehran
**Postal code**
**Approval date**
2016-06-12, 1395/03/23
**Ethics committee reference number**
IR.TUMS.VCR.1395.117

### 2

**Ethics committee**
**Name of ethics committee**
Added at 2017-03-05: Tehran University of Medical Sciences
**Street address**
Added at 2017-03-05:Tehran Province, Tehran, District 6, Pour Sina st
**City**
Added at 2017-03-05: Tehran
**Postal code**
1395/12/15 بروزرسانی
**Approval date**
empty
**Ethics committee reference number**
Added at 2017-03-05: IR.TUMS.REC.1395.2827

## Health conditions studied

### 1

**Description of health condition studied**
Kidney transplant
**ICD-10 code**
Z94.0
**ICD-10 code description**
Kidney transplant status

## Primary outcomes

### 1

**Description**
Regulatory T CD4+CD25+Foxp3+ cell
**Timepoint**
Before intervention and 4 months after intervention
**Method of measurement**
Flow cytometry technique

### 2

**Description**
Regulatory T CD8+CD28- cell
**Timepoint**
Before intervention and 4 months after intervention
**Method of measurement**
Flow cytometry technique

### 3

**Description**
Added at 2017-03-05: type 1 myeloid dendritic cells
**Timepoint**
Added at 2017-03-05: Before intervention and 4 months after
**Method of measurement**
Added at 2017-03-05: Flow cytometry technique

### 4

**Description**
Added at 2017-03-05: plasmacytoid dendritic cells
**Timepoint**
Added at 2017-03-05: Before intervention and 4 months after
**Method of measurement**

Added at 2017-03-05: Flow cytometry technique

### 5

**Description**
Added at 2017-03-05: T helper 17 cells
**Timepoint**
Added at 2017-03-05: Before intervention and 4 months after
**Method of measurement**
Added at 2017-03-05: Flow cytometry technique

### 6

**Description**
Added at 2017-03-05: T helper 1 cells
**Timepoint**
Added at 2017-03-05: Before intervention and 4 months after
**Method of measurement**
Added at 2017-03-05: Flow cytometry technique

### 7

**Description**
Added at 2017-03-05: T helper2 cells
**Timepoint**
Added at 2017-03-05: Before intervention and 4 months after
**Method of measurement**
Added at 2017-03-05: Flow cytometry technique

## Secondary outcomes

### 1

**Description**
Foxp3 gene
**Timepoint**
Before intervention and 4 months after intervention
**Method of measurement**
RT-PCR Technique

### 2

**Description**
T-bet gene
**Timepoint**
Before intervention and 4 months after intervention
**Method of measurement**
RT-PCR Technique

### 3

**Description**
RORγT gene
**Timepoint**
Before intervention and 4 months after intervention
**Method of measurement**
RT-PCR Technique

### 4

**Description**
GATA3 gene
**Timepoint**
Before intervention and 4 months after intervention
**Method of measurement**
RT-PCR Technique

### 5

**Description**
Added at 2017-03-05: Interferon gamma (IFNγ)
**Timepoint**
Added at 2017-03-05: Before intervention and 4 months after intervention
**Method of measurement**
Added at 2017-03-05: elisa technique

### 6

**Description**
Added at 2017-03-05: Interleukin-4
**Timepoint**
Added at 2017-03-05: Before intervention and 4 months after intervention
**Method of measurement**
Added at 2017-03-05: elisa technique

### 7

**Description**
Added at 2017-03-05: Interleukin-17A (IL-17A)
**Timepoint**
Added at 2017-03-05: Before intervention and 4 months after intervention
**Method of measurement**
Added at 2017-03-05: elisa technique

### 8

**Description**
Added at 2017-03-05: ILT4 gene
**Timepoint**
Added at 2017-03-05: Before intervention and 4 months after
**Method of measurement**
Added at 2017-03-05: RT-PCR Technique

### 9

**Description**
Added at 2017-03-05: ILT3 gene
**Timepoint**
Added at 2017-03-05: Before intervention and 4 months after intervention
**Method of measurement**
Added at 2017-03-05: RT-PCR Technique

### 10

**Description**
Added at: type 2 myeloid dendritic cells
**Timepoint**

Added at: Before intervention and 4 months after

**Method of measurement**

Added at: Flow cytometry technique

## Intervention groups

### 1

**Description**

Group A:patients take tacrolimus with Mycophenolic acid.give them 0.1 mg / kg Tacrolimus for 90 days to achieve 8-12 ng/ml plasma levels. then for achieveing 5-8ng/ml plasma level will adjust the dose.Mycophenolate Mofetil (500 mg in 3 divided doses for 7 days and then the dose of 1000 mg or equivalent) will increase.

**Category**

Treatment - Drugs

### 2

**Description**

Group B: pateints take tacrolimus with sirolimus. give them 0.8 mg/kg tacrolimus for 6 months to achieve6-7 ng/ml plasma levels and then4-5 ng/ml the plasma level will adjust the dose in the next 6 months. 2 mg of Sirolimus per 48 hours of surgery and then 1 mg per day to achieve3-5 ng/ml plasma levels in the first 6 months and then the dose to achieve 6-8 ng/ml plasma levels will increase .

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Labbafinezhad Hospital

**Full name of responsible person**

Dr. Pedram Ahmadpoor

**Street address**

Labbafinezhad Hospital, 9th Boostan, Pasdaran St.

**City**

Tehran

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Molecular Immunology Research Center

**Full name of responsible person**

Dr. Aliakbar Amirzargar

**Street address**

Molecular Immunology Research Center, Children's Medical Center, Keshavarz Blvd.

**City**

Tehran

**Grant name**

457 /1295،

**Grant code / Reference number**

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

Yes

**Title of funding source**

Molecular Immunology Research Center

**Proportion provided by this source**

**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*

### 2

**Sponsor**

**Name of organization / entity**

Behestan Pharmaceutical Company

**Full name of responsible person**

Dr.Younes Moradi

**Street address**

Behestan Pharmaceutical Company, Pardis St., Molla Sadra St., Vanak Square

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Behestan Pharmaceutical Company

**Proportion provided by this source**

**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*

### 3

**Sponsor**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Miss. Ahadi

**Street address**

Tehran University of Medical Sciences, Qhods St., Keshavarz blvd.

**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**
**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**
Tehran University of Medical Sciences
**Full name of responsible person**
Saeedeh Jamali
**Position**
Master of Medical Immunology
**Other areas of specialty/work**
**Street address**
Children's Medical Center, Keshavarz Blvd.
**City**
Tehran
**Postal code**
**Phone**
+98 21 8895 3009
**Fax**
**Email**
jamali.sa71@gmail.com; sjamali@razi.tums.ac.ir
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Dr. Aliakbar Amirzargar
**Position**
Professor
**Other areas of specialty/work**
**Street address**
Children's Medical Center, Keshavarz Blvd.
**City**
Tehran
**Postal code**
141556446
**Phone**
+98 21 8895 3009
**Fax**
+98 21 8895 3009
**Email**
Amirzara@sina.tums.ac.ir
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Tehran University of Medical Sciences
**Full name of responsible person**
Saeedeh Jamali
**Position**
Master of Medical Immunology
**Other areas of specialty/work**
**Street address**
Children's Medical Center, Keshavarz Blvd.
**City**
Tehran
**Postal code**
**Phone**
+98 21 8895 3009
**Fax**
**Email**
jamali.sa71@gmail.com; sjamali@razi.tums.ac.ir
**Web page address**

## 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*