

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

Compare changes two subsets of regulatory T cells (Treg) and gene expression of Foxp3, ROR γ T, 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, ROR γ T, 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, ROR γ T, 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

ROR γ T 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 (IFN γ)

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 achieving 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: patients take tacrolimus with sirolimus. give them 0.8 mg/kg tacrolimus for 6 months to achieve 6-7 ng/ml plasma levels and then 4-5 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 achieve 3-5 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 /12953

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

empty

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