

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Evaluation of Pharmacist Intervention for Improving Adherence of Immunosuppressive Regimen includes Calcineurin Inhibitors and Measuring Blood Levels of the Immunosuppressive Agents in Kidney Transplant Recipients

Protocol summary

Study aim

Determining the Effect of Pharmacist Intervention on the Rate of Adherence to Immunosuppression Regimens and Measuring the Level of Drug in Kidney Transplant Patients

Design

Clinical trial with control group, randomized, phase not applicable on 50 patients. Sealed envelope is used for randomization

Settings and conduct

This study was performed on 50 transplant patients in Labbafinejad Hospital. Our choice is in randomized way and the study was randomly controlled, with and without intervention

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient informed consent, age between 18 and 60 years, patients who have been transplanted for at least 3 years, taking immunosuppressive drugs; Exclusion criteria: unwillingness to continue studying, substance abuse, drug sensitivity, infection

Intervention groups

Intervention group: getting a manual along with consultation and visit of a pharmacist; Control group: Just get the manual

Main outcome variables

Adherence score in Morisky questionnaire, blood level of immunosuppressant drugs, fluctuation of blood concentrations in a certain period of time (IPV) of immunosuppressant drugs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150706023084N9**

Registration date: **2021-07-21, 1400/04/30**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-21, 1400/04/30**

Update count: **0**

Registration date

2021-07-21, 1400/04/30

Registrant information

Name

MARYAM SHIEHMORTEZA

Name of organization / entity

AZAD UNIVERSITY PHARMACEUTICAL SCIENCES

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-01, 1400/04/10

Expected recruitment end date

2021-08-01, 1400/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Pharmacist Intervention for Improving Adherence of Immunosuppressive Regimen includes

Calcineurin Inhibitors and Measuring Blood Levels of the Immunosuppressive Agents in Kidney Transplant Recipients		Shariati St., Pharmaceutical Sciences Branch, Islamic Azad University, Tehran		
Public title	Evaluation of Pharmacist Intervention for improving Adherence of Immunosuppressive Regimen in Kidney Transplant Recipients	City	Tehran	
		Province	Tehran	
		Postal code	193956466	
Purpose	Education/Guidance	Approval date	2020-07-05, 1399/04/15	
Inclusion/Exclusion criteria		Ethics committee reference number		
Inclusion criteria:		IR.IAU.PS.REC.1399.105		
Conscious satisfaction of the patient to participate in the study Age between 18 to 60 years Patients with kidney disease confirmed by doctors, kidney transplant have been done and at least 3 years have passed since their transplant Consumption of Immunosuppressive drug		Health conditions studied		
Exclusion criteria:		1		
Reluctance to continue participating in the study Drug abuse Drug allergy Infection		Description of health condition studied		
Age	From 18 years old to 60 years old	Kidney Transplant		
		ICD-10 code		
Gender	Both	Z94.0		
		ICD-10 code description		
Kidney transplant status				
Primary outcomes				
1		Description		
		Adherence score in the Morisky Questionnaire		
Randomization (investigator's opinion)		Timepoint		
Randomized		Measurement of adherence scores in the Morisky Questionnaire before the intervention and then in meetings at intervals of 2 months		
Randomization description		Method of measurement		
Randomization Method: Blocked Randomization Randomization Tool: Sealed envelope The allocation of individuals to the intervention or control groups will be carried out randomly, as it contains two forms with code A and two forms with code B, where each patient will be studied either with code A or code B in one of the groups.		The 8-item Morisky Medication Adherence Scale (MMAS-8)		
Blinding (investigator's opinion)		2		
Not blinded		Description		
Blinding description		blood levels of Immunosuppressive drugs		
Placebo		Not used	Timepoint	
Assignment		Parallel	Measurement of blood levels of Immunosuppressive drugs before the intervention and then at appointments at intervals of 2 months	
Other design features		Method of measurement		
		Blood test		
Secondary Ids		3		
empty		Description		
		Intra-Patient Variability (IPV) of Immunosuppressive drugs		
Ethics committees		Timepoint		
1		Measurement of Intra-Patient Variability (IPV) of Immunosuppressive drugs before the intervention and then at appointments at intervals of 2 months		
Ethics committee		Method of measurement		
Name of ethics committee		Percent of Mean Absolute Deviation (MAD) formula		
Ethics Committee of Pharmaceutical Sciences Branch of Tehran Islamic Azad University of Medical Scie				
Street address				
2. No. 199, Yasaman Alley, Yakhchal St., Gholhak, Dr.				

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: It consists of 25 people, each of whom, in addition to receiving a guidebook, includes all educational, behavioral and reinforcement actions and routine clinical appointments, benefits from the advice and support of a pharmacist. All interventions will be performed at a single center and the intervention in this group includes consultation and visit with a pharmacist to improve the patient's adherence to Immunosuppressive treatment regimen. These appointments will take place at least three years after the patient's transplant and at two-month intervals, and each patient will attend at least two appointments. In these appointments, the necessary advice is provided according to the patient's characteristics. At the appointments, measures such as taking the patient's medical history, completing the Morisky questionnaire, taking medication according to the doctor's instructions, socio-economic and Educational evaluation of the patient, measuring the patient's blood level of the drugs, identifying patient concerns about the drugs and answering patient questions, identification Possible causes of non adherence and efforts to resolve them, review the treatment regimen and the number of drugs required by the patient during this period will be done with the patient.

Category

Behavior

2

Description

Control group: It consists of 25 people, each of whom receives only a handbook including all educational, behavioral and reinforcement measures and clinical routine appointments. These appointments will take place at least three years after the patient's transplant and at two month intervals. During the appointments, there is no consultation or visit with the pharmacist to improve the patient's adherence to the Immunosuppressive treatment regimen, and individuals do not receive any intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Labbafinezhad Hospital

Full name of responsible person

Shiva Samavat

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9th Boostan St, Pasdaran St, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University, Pharmaceutical Sciences Branch

Full name of responsible person

Dr. Farshad Hashemian

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4. No. 3, Khaghani St., Shariati St., Islamic Azad University of Medical Sciences, Tehran

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Web page address

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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

Pharmaceutical Sciences Branch, Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Rokhshad Gharehcheloo

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

8. Pharmaceutical Sciences Branch, Islamic Azad University

Full name of responsible person

Maryam Shieh morteza

Position

PhD in Clinical Pharmacy

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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2. No. 199, Yasaman Alley, Yakhchal St., Gholhak, Dr. Shariati St., Pharmaceutical Sciences Branch, Islamic Azad University, Tehran

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

Rokhshad Gharehcheloo

Position

Student

Latest degree

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Email

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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