Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
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Name of organization / entity
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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

Public title
Evaluation of Pharmacist Intervention for improving Adherence of Immunosuppressive Regimen in Kidney Transplant Recipients
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
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
Exclusion criteria:
Reluctance to continue participating in the study Drug abuse Drug allergy Infection
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
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.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
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. Shariati St., Pharmaceutical Sciences Branch, Islamic Azad University, Tehran
City
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Tehran
Postal code
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Approval date
2020-07-05, 1399/04/15
Ethics committee reference number
IR.IAU.PS.REC.1399.105

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
Adherence score in the Morisky Questionnaire
Timepoint
Measurement of adherence scores in the Morisky Questionnaire before the intervention and then in meetings at intervals of 2 months
Method of measurement
The 8-item Morisky Medication Adherence Scale (MMAS-8)

2

Description
blood levels of Immunosuppressive drugs
Timepoint
Measurement of blood levels of Immunosuppressive drugs before the intervention and then at appointments at intervals of 2 months
Method of measurement
Blood test

3

Description
Intra-Patient Variability (IPV) of Immunosuppressive drugs
Timepoint
Measurement of Intra-Patient Variability (IPV) of Immunosuppressive drugs before the intervention and then at appointments at intervals of 2 months
Method of measurement
Percent of Mean Absolute Deviation (MAD) formula

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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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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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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Position
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Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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Position
Student

Latest degree
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Other areas of specialty/work
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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