# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Evaluation of effect of spironolactone on proteinuria in kidney transplant patients

### Protocol summary

**Study aim**
Evaluation of effect of spiranolactone on proteinuria in kidney transplant patients
**Design**
Two arm parallel group randomisedtrial with double blind care and outcome
**Settings and conduct**
Khorshid hospital,Al Zahra hospital and office
**Participants/Inclusion and exclusion criteria**
Entrance to study:Three month or more after kidney transplant with proteinuria more than 0.5 gram per day
Not to entrance to study: hypercalemia,sensitivity to drug gynechomastia,usage of drug for heart or liver failure estimated glomerular filtration rate below 30 military liter per minute
**Intervention groups**
Kidney transplant patients with proteinuria of more than 0.5 gram per day.For the patients in the first group as the intervention group, spironolactone 25 mg tablets will be started half daily and after one month it will be increased to one tablet daily and will be prescribed for a total of four months, and for the patients in the second group as the control group, placebo tablets will be prescribed for four months. becomes
**Main outcome variables**
Proteinuria

### General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20230516058205N1**
Registration date: **2023-07-06, 1402/04/15**
Registration timing: **registered_while_recruiting**

Last update: **2023-07-06, 1402/04/15**
Update count: **0**

**Registration date**
2023-07-06, 1402/04/15

**Registrant information**
**Name**
Pejman Poorshabanan najafabadi
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 31 3641 1396
**Email address**
pejmanpoorshabanan@hotmail.com

**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2023-06-22, 1402/04/01
**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**
Evaluation of effect of spironolactone on proteinuria in kidney transplant patients

**Public title**
Evaluation of effect of spironolactone on proteinuria in kidney transplant patients
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Persons with more than three months after kidney transplantation Proteinuria more than 0.5 gram per day

Estimated glomerular filtration rate more than 30 mili liter per minute Consent to participate in study

**Exclusion criteria:**

Serum potassium more than 5.5 Gynechomastia Transplant dysfunction(eGFR<30) Spironolactone usage for heart and liver failure sensitivity to spironolactone

**Age**

From **18 years** old

**Gender**

Both

**Phase**

4

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

For this purpose, random allocation software and block randomization method are used. In this method, 60 eligible patients are randomly divided into 30 blocks including 2 patients. Then, each of the 2 patients in the block randomly receives spironolactone or placebo, so that 30 patients are assigned to each group.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients will be divided into two groups using random allocation software. Then, for the patients in the first group as the intervention group, spironolactone 25 mg tablets will be started half daily and after one month it will be increased to one tablet daily and will be prescribed for a total of four months, and for the patients in the second group as the control group, the placebo tablets will be prescribed for four months. It is prescribed. It should be noted that in order to comply with the conditions of blinding, the two drugs spironolactone and placebo are made in advance by the pharmacist (Abourihan Pharmaceutical Company) in the same shape, size and color and are placed in similar packages and labeled A, B at the disposal of the researcher. is placed and without knowing the type of medicine, they prescribe the same in two groups

**Placebo**

Used

**Assignment**

Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Isfan University of medical sciences

**Street address**

Heparin jarib

**City**

Isfahan

**Province**

Isfehan

**Postal code**

۸۱۷۴۶۷۳۴۶۱

**Approval date**

2023-04-18, 1402/01/29

**Ethics committee reference number**

IR.ari.mui.rec.1402.021

## Health conditions studied

### 1

**Description of health condition studied**

Proteinuria

**ICD-10 code**

N08

**ICD-10 code description**

Glomerular disorders in diseases classified elsewhere

## Primary outcomes

### 1

**Description**

Urine protein

**Timepoint**

Monthly

**Method of measurement**

24 hours urine sample

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: For the patients in the first group as the intervention group, spironolactone 25 mg tablets will be started half daily and after one month it will be increased to one tablet daily and it will be prescribed for a total of four months,

**Category**

Treatment - Drugs

**2**

**Description**
Control group: For the patients in the second group as the control group, the placebo tablets will be administered for four months.
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Khorshid hospital
**Full name of responsible person**
Pejman Pourshabanan Najafabadi
**Street address**
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Esfahan University of Medical Sciences
**Full name of responsible person**
Dr.Gholamreza Askari
**Street address**
Hezar jarib street
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**Province**
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8174673461
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**Email**
Askari@mui.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Esfahan 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**
Esfahan University of Medical Sciences
**Full name of responsible person**
Abdolamir Atapour
**Position**
associate professor
**Latest degree**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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Esfahan University of Medical Sciences

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Pejman Poorshabanan Najafabadi

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fellowship

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Specialist

**Other areas of specialty/work**
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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
Yes - There is a plan to make this available

**Study Protocol**
Yes - There is a plan to make this available

**Statistical Analysis Plan**
Yes - There is a plan to make this available

**Informed Consent Form**
Yes - There is a plan to make this available

**Clinical Study Report**
Yes - There is a plan to make this available

**Analytic Code**
Yes - There is a plan to make this available

**Data Dictionary**
Yes - There is a plan to make this available

**Title and more details about the data/document**
All data can be released after making persons unidentifiable.

**When the data will become available and for how long**
Begining access period time from 1403.

**To whom data/document is available**
Researchers who are occupying in universities and scientific institutes

**Under which criteria data/document could be used**
Results of this study can be used in other researches.

**From where data/document is obtainable**
pejmanpoorshabanan@hotmail.com

**What processes are involved for a request to access data/document**
One month after receiving request , we will send the results of this study.

**Comments**