

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluation of effect of spironolactone on proteinuria in kidney transplant patients

Protocol summary

Study aim

Evaluation of effect of spironolactone on proteinuria in kidney transplant patients

Design

Two arm parallel group randomised trial 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 gynecomastia, usage of drug for heart or liver failure estimated glomerular filtration rate below 30 milliliters 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

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Heparin jarib

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Isfahan

Province

Isfahan

Postal code

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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

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Second apadana Street.welfare organization of Isfahan province

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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

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Hezar jarib street

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8174673461

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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

Subspecialist

Other areas of specialty/work

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Latest degree

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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

Beginning 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