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 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)
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+98 31 3641 1396
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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
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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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Province
Isfehan
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8174673461
Phone
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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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Position
fellowship

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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