Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of kidney transplant with N-Acety Cystein (NAC) and Selenium supplement on sexual hormone profile and sexual function in end stage renal disease patinas

Protocol summary

Study aim

The effect of kidney transplant with N-Acety Cystein (NAC) and Selenium supplement on sexual hormone profile and sexual function in end stage renal disease patients

Design

A randomized double blinded controlled clinical trial with a parallel group design of 50 patients, enrolled between september 2020 until december 2020

Settings and conduct

Double-blind clinical trial will be done in the transplant department of modarres hospital, the patients with renal failure and gonadal dysfunction under the age of 50 with kidney problems divided to control and intervention group, random sampling is doing with blocking method. the intervention group will be taking N-acetyl cysteine and selenium and the control group will be taking placebo during intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Hemodialysis male patients (under 50) with gonadal dysfunction Exclusion criteria: Patients with specific pathologic, varicocele, leukospermia, other hormonal problems thyroid disease, smoking, alcohol user, urinary tract obstruction, cryptorchidism, vasectomy, cancer patients, treated with psychiatric drugs and diabetes.

Intervention groups

Intervention group: Patients with renal insufficiency and gonadal dysfunction are treated with N-Acetylcysteine and Selenium, after renal transplantation. control group : Patients with renal insufficiency and gonadal dysfunction after renal transplantation with placebo.

Main outcome variables

Status of sex hormones including Testosterone LH and FSH hormones and sperm and prolactin analysis and questionnaire (the international index of erectile function)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200427047218N1**
Registration date: **2020-07-01, 1399/04/11**
Registration timing: **prospective**

Last update: **2020-07-01, 1399/04/11**
Update count: **0**

Registration date

2020-07-01, 1399/04/11

Registrant information

Name

mahboubeh mashayekhi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2225 6428

Email address

mmashayekhi@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-22, 1399/06/01

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of kidney transplant with N-Acety Cystein (NAC) and Selenium supplement on sexual hormone profile and sexual function in end stage renal disease patinas

Public title
Effect of kidney transplantation in combination with N-Acetyl Cysteine and selenium Supplements on gonadal function in renal disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Men aged 15-50 years having kidney failure With sexual dysfunction
Exclusion criteria:
Diabetic patients history of Varicocele history of Vasectomy Advanced cardiopulmonary disease History of neuropsychiatric drugs

Age
From **15 years** old to **50 years** old

Gender
Male

Phase
3

Groups that have been masked

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

Sample size
Target sample size: **50**
More than 1 sample in each individual
Number of samples in each individual: **3**
The following tests will be carried out at baseline, after kidney transplantation and before discharge and also six months after transplantation. Sexual hormones including Prolactin, Luteinizing Hormone (LH), Testosterone, Dehydroepiandrostrone and Follicle-Stimulating Hormone (FSH) will be measured. Protamin content and DNA integrity will be evaluated by semen analysis technique and the WHO-2010 criteria. In addition, sexual functions will be assessed using modified International Index of Erectile Function (IIEF).

Randomization (investigator's opinion)
Randomized

Randomization description
In order to balance random allocation of subjects between study groups, we will use randomized blocks with unequal sizes of 2 or 4 patients. List of all possible permutations will be prepared and then required number of them will be selected randomly. This will be done using appropriate piece of software or a valid websites.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this double blind study, similar packages will be provided for supplements and placebo; the only difference between them will be the codes written on the pack. Patients, principal investigator, residents and those involved in patients physical exam and interview will be remained blind. The only person who will be aware of the packs content, is the ward staff. She will be asked not to reveal the codes till the end of study when all required data are collected.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Behshti University of Medical Sciences
Street address
Modares Hospital, Saadat Abad Ave., Saadat Abad Blvd.
City
Tehran
Province
Tehran
Postal code
1998734383

Approval date
2020-02-23, 1398/12/04

Ethics committee reference number
IR.SBMU.RETECH.REC.1398.837

Health conditions studied

1

Description of health condition studied
Patients with renal insufficiency who need a kidney transplant and have sexual dysfunction problems

ICD-10 code
N18.5

ICD-10 code description
Chronic Kidney Disease, Stage 5

Primary outcomes

1

Description
International erection performance index questionnaire

Timepoint
Before transplantation and medication and 6 months later

Method of measurement
questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: patients with renal insufficiency treated with renal transplantation in conjunction with N-Acetyl Cysteine 600 mg (Hakim pharmacy)and Selenium 200 µg (21st century factory)supplements daily during six month.
Category
Treatment - Surgery

2

Description
Control group: Patients with renal insufficiency undergoing renal transplantation with sexual dysfunction problems who receive the placebo instead of N-Acetyl cysteine and selenium
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Modares Hospital
Full name of responsible person
Mahboubeh Mashayekhi
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Modares Hospital, Saadat Abad Ave., Saadat Abad Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mahboubeh Mashayekhi
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

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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
The available information in this field include Laboratory data an complete fill up questionnaires that will be done by patients finally enable to share potentially.
When the data will become available and for how long
The course will start from the second half of 1399 to the end of 1399
To whom data/document is available
For academic and scientific institutions will be available, also for people who are working in the industry
Under which criteria data/document could be used
Any statistical analysis and use of research project information is allowed
From where data/document is obtainable
Modares hospital, saadat abad ave., Saadat Abad Blvd.
What processes are involved for a request to access data/document
Maximum 6 months
Comments