

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 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)

##### Phone

+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 months.

#### 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

##### Street address

Modares Hospital, Saadat Abad Ave., Saadat Abad Blvd.

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##### Postal code

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##### Phone

+98 21 2243 9913

##### Email

mmashayekhi@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Mahboubeh Mashayekhi

##### Street address

Modares Hospital, Saadat Abad Ave., Saadat Abad Blvd.

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#### Phone

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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

##### Street address

Modares Hospital, Saadat Abad Ave., Saadat Abad Blvd.

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## Person responsible for scientific 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**

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**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Amir Hessam Alirezaei

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**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**

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**