

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jun 2026

Comparison of sexual dysfunction in renal transplant recipients with the internal and external iliac anastomosis

Protocol summary

Study aim

Comparison of sexual dysfunction in renal transplant recipients with the internal and external iliac anastomosis

Design

A double-blind clinical trial, with parallel, randomized groups, on 60 patients, used random allocation software for randomization.

Settings and conduct

Double-blind (participant and data analyzer). Male and married patients under 60 years of age are candidates for kidney transplant surgery by two methods of internal and external iliac artery anastomosis in September and October of 2020 in Khorshid and Al-Zahra centers of Isfahan who are satisfied to participate in the study and if during surgery or They die during the study, have a transplant rejection, are unable to access them for any reason, or do not want to continue participating in the study. They are excluded from the study using random assignment software to two groups of internal iliac artery anastomoses. And are divided externally. The number of samples in each group is 30. At the final visit before surgery, the IIEF questionnaire will be provided to them. Six months and one year after each surgery, the IIEF questionnaire is completed again by the patients. Subsequently, all information is entered in SPSS 23 statistical software and analyzed by repeated measures statistical test and post hoc tests.

Participants/Inclusion and exclusion criteria

Married male patients less than 60 years old who are candidates for kidney transplant surgery will be examined by two methods of internal and external iliac artery anastomosis who are willing to participate in the study. Patients who died during surgery or the follow-up period were rejected during the study, for whatever reason are reluctant to continue the study, or are not available for follow-up after surgery are excluded from the study.

Intervention groups

Two surgical methods of internal and external iliac artery anastomosis

Main outcome variables

Sexual dysfunction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200804048296N1**

Registration date: **2020-08-06, 1399/05/16**

Registration timing: **prospective**

Last update: **2020-08-06, 1399/05/16**

Update count: **0**

Registration date

2020-08-06, 1399/05/16

Registrant information

Name

Amir Javid

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3234 9802

Email address

amirjavid@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-31, 1399/06/10

Expected recruitment end date

2020-10-01, 1399/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of sexual dysfunction in renal transplant recipients with the internal and external iliac anastomosis

Public title

sexual dysfunction in renal transplant with the internal and external iliac anastomosis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who are candidates for kidney transplant surgery using internal and external iliac artery anastomosis methods Married male patients less than 60 years old Have consent to participate in the study

Exclusion criteria:

Patients whose long-term follow-up is not possible for any reason, such as distance from home

Age

To **60 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Using random allocation software to divide patients into two groups, internal and external iliac artery anastomosis

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants: they do not know about arterial anastomosis method (internal or external iliac) in their kidney transplant surgery. Data analyzer: does not know what surgical procedure each of the data relates to.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of isfahan University of Medical Sciences

Street address

Hezarjarib street

City

isfahan

Province

Isfahan

Postal code

۸۱۷۴۶۷۳۴۶۱

Approval date

2020-08-02, 1399/05/12

Ethics committee reference number

IR.MUI.MED.REC.1399.363

Health conditions studied**1****Description of health condition studied**

Sexual dysfunction

ICD-10 code

F52

ICD-10 code description

Sexual dysfunction not due to a substance or known physiological condition

Primary outcomes**1****Description**

Sexual ability score in the International Index of Erectile Function (IIEF) questionnaire

Timepoint

Before kidney transplant surgery, 6 months and one year after

Method of measurement

International Index of Erectile Function (IIEF) questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Use of end-to-end internal iliac artery anastomosis for blood supply to a transplanted kidney in kidney transplant surgery

Category

Treatment - Surgery

2

Description

Control group: Use of end-to-side external iliac artery anastomosis for blood supply to a transplanted kidney in kidney transplant surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-zahra hospital

Full name of responsible person

Amir Javid

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2

Recruitment center

Name of recruitment center

Khorshid hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooyejavanmard

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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

Amir Javid

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Urology

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Information about the IIEF questionnaire of the studied patients

When the data will become available and for how long

Access period starts 3 months after the results are published

To whom data/document is available

Only for researchers working in academic institutions

Under which criteria data/document could be used

The terms of use of the data have not yet been decided.

From where data/document is obtainable

Dr. Amir Javid (Executor) amirjavid@med.mui.ac.ir

What processes are involved for a request to access data/document

Sending an email to the project manager, investigating the reason for requesting the data by the project manager, the research council of the urology department and the university

Comments