

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 2026

### Comparison of surgical outcomes and quality of life in patients after laparoscopic donor nephrectomy versus open surgery

#### Protocol summary

##### Study aim

Comparison of surgical outcomes and quality of life in patients after laparoscopic donor nephrectomy versus open surgery

##### Design

A non-blinded randomized clinical trial (open label) with parallel groups will be conducted on 88 participants. The participants will be randomly allocated to one of the surgical groups, laparoscopic or open, using random allocation software.

##### Settings and conduct

In this study, kidney transplant patients (Kidney donors) will be enrolled at Urmia Imam Khomeini Hospital. The study will be conducted without blinding.

##### Participants/Inclusion and exclusion criteria

In this clinical trial, 88 kidney transplant patients (kidney donors) of any age and gender will be enrolled.

##### Intervention groups

Surgery will be performed laparoscopically in one group and open surgery in another group.

##### Main outcome variables

Kidney function; level of satisfaction; quality of life; post-surgical complications.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180625040232N10**

Registration date: **2023-06-21, 1402/03/31**

Registration timing: **prospective**

Last update: **2023-06-21, 1402/03/31**

Update count: **0**

##### Registration date

2023-06-21, 1402/03/31

#### Registrant information

##### Name

Saman Farshid

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 44 3346 9931

##### Email address

farshid.s@umsu.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

##### Expected recruitment start date

2023-08-23, 1402/06/01

##### Expected recruitment end date

2024-03-19, 1402/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

#### Scientific title

Comparison of surgical outcomes and quality of life in patients after laparoscopic donor nephrectomy versus open surgery

#### Public title

Comparison of surgical outcomes in laparoscopic donor nephrectomy versus open surgery

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Kidney donors No complexity in the donor kidney vessels  
Recipient aged 18-65 years

##### Exclusion criteria:

History of abdominal surgery Coagulation disorders

having a collateral artery branch in CT angiography  
Haemolytic uraemic syndrome Focal segmental  
glomerulosclerosis and oxalosis in the recipient.

#### Age

No age limit

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: 88

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

Participants will be randomly assigned to one of the laparoscopic or open surgical groups using computer-generated numbers produced by the Random allocation software. Thus, in this software, the number of groups and the total sample size will be entered, and then the "randomization" will be implemented in the block section. Then, the computer-generated number list will be given to the physician, and the physician will assign patients to groups according to the determined order by the software for entry into one of the groups. For example, if the first patient in the generated list is assigned to the laparoscopic surgery group, the next patient may be placed in either the laparoscopic or open surgery group. Thus, the randomization process will continue until the final sample size is reached.

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Imam Khomeini University  
hospital- Urmia University of Medical Sciences

##### Street address

Imam Khomeini hospital, Ershad Ave, Modarres Blvd,  
Urmia, Iran.

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

57157-89397

#### Approval date

2022-10-11, 1401/07/19

#### Ethics committee reference number

IR.UMSU.HIMAM.REC.1401.063

## Health conditions studied

### 1

#### Description of health condition studied

Clinical outcomes and quality of life in laparoscopic donor  
nephrectomy versus open surgery

#### ICD-10 code

-

#### ICD-10 code description

-

## Primary outcomes

### 1

#### Description

Kidney function (patient's urine output volume from the  
start of the surgery to 24 hours after surgery)

#### Timepoint

Within 24 hours after surgery

#### Method of measurement

Liter

### 2

#### Description

Patient`s satisfaction

#### Timepoint

One year after surgery

#### Method of measurement

Surgical satisfaction Questionnaire-8 (SSQ-8)

### 3

#### Description

Quality of life

#### Timepoint

One year after surgery

#### Method of measurement

SF36 questionnaire

### 4

#### Description

Fever

#### Timepoint

Within 24 hours after surgery

#### Method of measurement

Clinical examination

### 5

#### Description

Decrease in hemoglobin levels

#### Timepoint

Within 24 hours after surgery

#### Method of measurement

Clinical examination

## **6**

### **Description**

Urinary retention

### **Timepoint**

Within 24 hours after surgery

### **Method of measurement**

Clinical examination

## **Secondary outcomes**

## **1**

### **Description**

Length of hospitalization

### **Timepoint**

The number of days of hospitalization after the surgery

### **Method of measurement**

Medical records

## **2**

### **Description**

Time to return to work

### **Timepoint**

Time from discharge to return to work

### **Method of measurement**

Interview

## **3**

### **Description**

Hemoglobin

### **Timepoint**

Within 24 hours after the surgery

### **Method of measurement**

Blood test

## **Intervention groups**

## **1**

### **Description**

Intervention group: Surgery will be performed laparoscopically in one group.

### **Category**

Treatment - Surgery

## **2**

### **Description**

Intervention group: Surgery will be performed as open surgery in another group.

### **Category**

Treatment - Surgery

## **Recruitment centers**

## **1**

### **Recruitment center**

#### **Name of recruitment center**

Imam Khomeini hospital

#### **Full name of responsible person**

DR. Saman Farshid

#### **Street address**

Imam Khomeini hospital, Ershad Ave, Modarres Blvd, Urmia, Iran.

#### **City**

Urmia

#### **Province**

West Azarbaijan

#### **Postal code**

57154-89397

#### **Phone**

+98 44 3345 7286

#### **Email**

farshid.s@umsu.ac.ir

## **Sponsors / Funding sources**

## **1**

### **Sponsor**

#### **Name of organization / entity**

Oroumia University of Medical Sciences

#### **Full name of responsible person**

Dr.Saber Gholizadeh

#### **Street address**

Urmia University of Medical Sciences, Resalat Ave, Jahad Blvd, Urmia, Iran.

#### **City**

Urmia

#### **Province**

West Azarbaijan

#### **Postal code**

5714783734

#### **Phone**

+98 44 3223 3009

#### **Email**

gholizadeh.s@umsu.ac.ir

### **Grant name**

### **Grant code / Reference number**

### **Is the source of funding the same sponsor organization/entity?**

Yes

### **Title of funding source**

Oroumia 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**

Oroumia University of Medical Sciences

**Full name of responsible person**

Dr. Saman Farshid

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Urology

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Confidentiality of patient information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

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

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The results of the study will be published as an article.

**When the data will become available and for how long**

After publishing the article

**To whom data/document is available**

Researchers

**Under which criteria data/document could be used**

The results will be published as an article and the data will not be published.

**From where data/document is obtainable**

Corresponding author

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

By email address of the corresponding author:farshid.s@umsu.ac.ir

**Comments**