

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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.

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Phone

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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, Jihad Blvd, Urmia, Iran.

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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

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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