Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of efficacy and safety of mini-laparoscopy and standard laparoscopy in kidney donors

Protocol summary

Summary

Objective: We can introduce Mini-laparoscopic donor nephrectomy as an acceptable alternative for standard or laparoendoscopic single site surgery (LESS) if our results reveal good peri and postoperative outcomes with acceptable graft survival. Design: After pilot study using 20 donors and assessment of primary results, a single blind randomized clinical trial was designed. Setting and conduct: This project will be performed in two groups of donors (50 cases in each group) who undergo standard and mini laparoscopic surgery. Each donor and related recipient will be followed for three months for glomerular filtration rate (GFR), serum creatinine, blood pressure and cosmetic appearance of scars. Participants including major eligibility criteria: The cases who candidate for laparoscopic donor nephrectomy Exclusion criteria: Right donor nephrectomy, vascular anomaly, previous history of laparotomy Intervention: Standard laparoscopic donor nephrectomy in one group and Mini-laparoscopic donor nephrectomy in the other group Main outcome measures (variables): Warm ischemic time - Hospital stay - Operative time - Blood pressure in recipient - Cosmetic appearance of trocars scar three months after operation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201207187457N10**
Registration date: **2012-10-08, 1391/07/17**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-10-08, 1391/07/17

Registrant information

Name
Shabnam Golshan
Name of organization / entity
Urology and Nephrology Research Center (UNRC)
Country
Iran (Islamic Republic of)
Phone
+98 21 2256 7222
Email address
shgolshan@unrc.ir

Recruitment status

Recruitment complete

Funding source

This project will be supported by BMN (Bonyad Melli Nokhbegan) and UNRC (Urology and nephrology research center of Shahid Behshti Medical University).

Expected recruitment start date

2012-08-21, 1391/05/31

Expected recruitment end date

2013-02-21, 1391/12/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and safety of mini-laparoscopy and standard laparoscopy in kidney donors

Public title

Importance of Mini-laparoscopy in kidney donation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The cases who candidate for laparoscopic donor nephrectomy. Exclusion criteria: Right donor nephrectomy, vascular anomaly, previous

history of laparotomy

Age

From **18 years** old to **45 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Kind of randomization: Simple random sampling

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Urology and Nephrology Research Center (UNRC) related to Shahid Beheshti Medical University (SBMU)

Street address

No#103, 9th Boostan St., Pasdaran Ave.

City

Tehran

Postal code

Approval date

2012-05-31, 1391/03/11

Ethics committee reference number

41573/الف/ت/م

Health conditions studied

1

Description of health condition studied

Renal failure (kidney donation to patients with ESRD)

ICD-10 code

N17- N18 -

ICD-10 code description

Kidney damage with severely decreased GFR (15-29 mL/min)

Primary outcomes

1

Description

Warm ischemic time

Timepoint

During operation

Method of measurement

From renal artery clamping to beginning of cold saline irrigation

2

Description

Hemoglobin

Timepoint

Before operation - the day after operation - at discharge time

Method of measurement

Laboratory test (CBC)

3

Description

Admission time

Timepoint

From operation to discharge

Method of measurement

Number of admission day

4

Description

Appearance of trocars scar

Timepoint

Three months after operation

Method of measurement

Observation and determination of scars

5

Description

GFR in recipient

Timepoint

Three months after operation

Method of measurement

Kortchof formula

6

Description

Blood pressure in donor

Timepoint

Three months after operation

Method of measurement

Using assessment of blood pressure

Secondary outcomes

1

Description

Bleeding

Timepoint

During operation and in recovery room

Method of measurement

Regarding to the measurement of blood extracted from the suction

2

Description

Requirement to analgesic and opium

Timepoint

In recovery room and unit admission

Method of measurement

Assessment of dose injected IM or IV

3

Description

Visceral injury

Timepoint

During operation

Method of measurement

According to direct vision of injury or delayed manifestations in postoperative days

Intervention groups

1

Description

Control group: 50 patients who underwent laparoscopic standard donor nephrectomy Laparoscopic standard nephrectomy: this operation is performed using one 12 mm port for video scope, two 5 mm for grasping and scissoring and one 10 mm port for vascular clipping. The specimen is extracted from pfananestiel incision.

Category

Treatment - Surgery

2

Description

Intervention group: 50 patients who underwent donor nephrectomy using mini-laparoscopic approach. Mini-laparoscopic approach: This operation is performed using two 3.5 mm ports for grasping and scissoring, one 5 mm port for video scope and one 10 mm port in the pfanenstiel incision.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Labbafinejad Medical Center

Full name of responsible person

Mohammad Hossein Soltani

Street address

Shahid Labbafinejad Medical Center - Boostan 9th St. - Pasdaran Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

BMN (Bonyad Melli Nokhbegan)

Full name of responsible person

Mrs Jaafari

Street address

No#11, Shirkouh Alley, Zafaranieh St., Valli-asr Ave.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

BMN (Bonyad Melli Nokhbegan)

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

2

Sponsor

Name of organization / entity

Urology and Nephrology Research Center, Vice chancellor for research of Shahid Behesti University of

Full name of responsible person

Mrs Golshan

Street address

No#103, Boostan 9th St., Pasdaran Ave.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Urology and Nephrology Research Center, Vice chancellor for research of Shahid Behesti University of

Proportion provided by this source

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Labbafinejad Medical Center
Full name of responsible person
Mohammad Hossein Soltani
Position
Urologist
Other areas of specialty/work
Street address
No#99, Boostan 9th St., Pasdaran Ave.
City
Tehran
Postal code
Phone
+98 21 2258 8016
Fax
+98 21 2258 8016
Email
mhsoltani@iurtc.org.ir
Web page address
www.iurtc.org.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shahid Labbafinejad Medical Center
Full name of responsible person
Nasser Simforoosh
Position
Fellowship of pediatric urology and kidney transplantation
Other areas of specialty/work
Street address
No#99, Boostan 9th St., Pasdaran Ave.
City
Tehran
Postal code
Phone
+98 21 2258 8016
Fax
+98 21 2258 8016
Email
simforoosh@iurtc.org.ir
Web page address
www.iurtc.org.ir

Person responsible for updating data

Contact
Name of organization / entity
Shahid Labbafinejad Medical Center
Full name of responsible person
Mohammad Hossein Soltani
Position
Urologist
Other areas of specialty/work
Street address
No#99, Boostan 9th St., Pasdaran Ave.
City
Tehran
Postal code
Phone
+98 21 2258 8016
Fax
+98 21 2258 8016
Email
mhsoltani@iurtc.org.ir
Web page address
www.iurtc.org.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty