

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Randomized clinical trial comparing the effect of removing the double-J stent without cystoscopy with attaching it to Foley catheter after kidney transplantation

Protocol summary

Study aim

The ureteric stent can be attached to the Foley catheter in the kidney transplantation to exclude the cystoscopy for its removal. There has been no randomized trial to evaluate the effect of this attachment on the major urologic complications.

Design

A concealed, randomized, non-blinded, clinical trial with a parallel group design of 163 patients, enrolled between March 2016 and June 2017 and followed for nine months. Randomization is done with the concealed envelopes. The treatment methods are not blinded to the surgeon and the patients.

Settings and conduct

The study are carried out in Labbafinejad Medical Center, Tehran, Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients more than 15 years old who are the candidate for renal transplantation in the Labbafinejad Medical Center during the study period; informed consent. Exclusion criteria: patients with a history of neurogenic bladder, BPH, bladder surgery; After revascularization and before ureteroneocystostomy if the surgeon feels that the patient is not suitable for attaching the Foley to the stent (like fear of hemorrhage); Postoperatively if there is an extended urinary leak which necessitates the stent removal after seven days.

Intervention groups

Patients are divided randomly with the concealed envelopes to intervention and control groups. the Intervention group: the stent is attached to the Foley catheter and removed together. Control group: stent removal is done by cystoscopy. Seven days after the transplant, the stent is removed in both groups.

Main outcome variables

The primary outcomes are major urologic complications

(MUCs), i.e., urinary leak, and ureteric obstruction which needed an intervention for treatment. The secondary outcome is pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100313003547N6**

Registration date: **2019-04-15, 1398/01/26**

Registration timing: **retrospective**

Last update: **2019-04-15, 1398/01/26**

Update count: **0**

Registration date

2019-04-15, 1398/01/26

Registrant information

Name

Mohammad Nadjafi-Semnani

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Urology- Nephrology Research Center – Shahid Beheshti University of Medical Sciences. Tehran - Iran

Expected recruitment start date

2016-03-01, 1394/12/11

Expected recruitment end date

2017-06-15, 1396/03/25
Actual recruitment start date
 2016-03-01, 1394/12/11
Actual recruitment end date
 2017-06-15, 1396/03/25
Trial completion date
 2018-12-25, 1397/10/04

Scientific title
 Randomized clinical trial comparing the effect of removing the double-J stent without cystoscopy with attaching it to Foley catheter after kidney transplantation

Public title
 Effect of removing the double J stent without cystoscopy after kidney transplantation

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with age less than 76 years; Patients with age more than 15 years; All patients who are candidate for renal transplantation by surgeons in the Labbafinejad hospital.
Exclusion criteria:
 Neurogenic bladder History of surgery in urinary bladder History of bladder outlet obstruction by Benign Prostatic Hyperplasia (BPH) After revascularization and before ureteroneocystostomy if the surgeon feels that there is need for stent to be removed later than 7 days Multiple renal arteries urinary leak that warrant stent removal later than 7 days.

Age
 From **16 years** old to **75 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **170**
 Actual sample size reached: **163**

Randomization (investigator's opinion)
 N/A

Randomization description

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
 Urology Nephrology Research Center- Shahid Beheshti Medical University
Street address
 Pasdaran St. - 9th Nostan St.
City
 Tehran
Province
 Tehran
Postal code
 1666663731
Approval date
 2017-02-13, 1395/11/25
Ethics committee reference number
 IR.SBMU.UNIRC.1395.21

Health conditions studied

1
Description of health condition studied
 Kidney Transplantation
ICD-10 code
 Z94.0
ICD-10 code description
 Kidney transplant status

Primary outcomes

1
Description
 Major Urologic Complications (MUC) including urinary leak and ureteral obstruction
Timepoint
 Nine months. After discharge, one a week for a month, then every other week for next tow months and then monthly patients will be seen in the clinic
Method of measurement
 Urinary leak is defined clinically by urine leak through the surgical drain and is confiremd by measuring urine creatinine and by delayed DTPA radionucleic scan. Ureteral obstruction is defined by rising of serum creatinine and finding of obstruction in ultrasonography scan or ante-grade nephrostography.

Secondary outcomes

1
Description
 creatinine level in serum
Timepoint
 one month, 6 months and 12 months after kidney transplantation
Method of measurement
 laboratory measurments

2

Description

Pain experienced during the stent removal

Timepoint

At the stent removal time during first ten days of transplantation

Method of measurement

Pain is measured by visual analogue scale (VAS)

3

Description

The cost of treatment

Timepoint

Three weeks

Method of measurement

The cost of cystoscopy procedure for stent removal is confirmed by hospital administration.

Intervention groups

1

Description

In the intervention group, the double J stent is removed without flexible cystoscopy by attaching the Foley catheter to a double J stent during the operation.

Category

Treatment - Devices

2

Description

Control group: In the control group, the double J stent is removed with the help of flexible or rigid cystoscopy in the operation room.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Labbafinejad Medical Centre

Full name of responsible person

Mohammad Nadjafi-Semnani

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Ninth Boostan Ave.- Pasdaran St. Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Ms Golshani

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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 Labafinejad Medical Center, Shahid Beheshti Medical University

Full name of responsible person

Mohammad Nadjafi-Semnani

Position

Associate Professor of Urology

Latest degree

Subspecialist

Other areas of specialty/work

Urology

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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
The study started before 2019
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available