

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

22 Jun 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)

##### Phone

+98 21 8863 9551

##### Email address

nadjafi@hbi.ir

##### 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 clinicaly 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

##### **Street address**

Ninth Boostan Ave.- Pasdaran St. Tehran

##### **City**

Tehran

##### **Province**

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##### **Postal code**

1666663111

##### **Phone**

+98 21 2258 8016

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##### **Email**

nadjafi@sbmu.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Shahid Beheshti University of Medical Sciences

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

Ms Golshani

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##### **Email**

Simforoosh@iurtc.org.ir

#### **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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## Person responsible for scientific inquiries

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Shahid Labafinejad Medical Center, Shahid Beheshti Medical University  
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Mohammad Nadjafi-Semnani  
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## Person responsible for updating data

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Shahid Beheshti University of Medical Sciences  
**Full name of responsible person**  
Mohammad Nadjafi-Semnani  
**Position**  
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nadjafi@sbmu.ac.ir  
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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