Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Investigation of Urinary Symptoms, Biofilm Formation, and Encrustation in Extra Double J Stents compared to the Standard Method: A clinical trial

Protocol summary

Study aim

investigate the incidence of urinary tract symptoms , biofilm formation and encrustation in extra Stent Double j in comparison with standard method.

Design

A total of 80 people will be included in the study, who will be divided into two groups: control and intervention. The clinical trial is single-blind. Randomization will be performed using the balanced block randomization method in four-blocks to allocate to two intervention and two control groups. After the randomization sequence is prepared by the methodologist and using the online site Seal Denvelop, the created sequence will be provided to a technician outside the research team.

Settings and conduct

This clinical trial will be conducted at Sina Hospital, Urology Research Center, on 80 patients. The first group, the control group, will receive standard double-G stents, and the second group, the intervention group, will receive extra double-j stents.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 40 male patients over 18 years of age who have kidney stones and require placement of a double J stent in the ureter for treatment. Exclusion criteria: Patients with active urinary tract infection or systemic infection at the time of stent placement. Patients with severe chronic kidney disease. Patients with a history of complex ureteral surgeries or severe anatomical abnormalities that may affect stent placement.

Intervention groups

The first control group will receive 40 patients with standard double-gauge stents. The second intervention group will receive 40 patients with extra double-gauge stents.

Main outcome variables

urinary tract symptoms (pain, irritation, urinary frequency & urgency)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190624043991N38**
Registration date: **2026-04-22, 1405/02/02**
Registration timing: **prospective**

Last update: **2026-04-22, 1405/02/02**
Update count: **0**

Registration date

2026-04-22, 1405/02/02

Registrant information

Name

Seyed Mohammad Kazem Aghamir

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 6634 8560

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mkaghamir@tums.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

Expected recruitment end date

2027-08-23, 1406/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of Urinary Symptoms, Biofilm Formation, and Encrustation in Extra Double J Stents compared to the Standard Method: A clinical trial

Public title
Assessment of using Extra Double J Stents complications in comparison with standard method.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
patients who needs treatment with Double J Stents Male sexuality Patients elder than 18 years old
Exclusion criteria:
Patients with active or systemic infection in urinary tract Patients who suffer from chronic kidney diseases Patients with history of complicated urethra surgery or anatomic abnormality that effect Double J Stents installation
Age
From **18 years** old
Gender
Male

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Using the Random Allocation Software, a list of random allocations to two groups is created. This list is organized into small blocks (blocks of 4) to maintain a balance of patients in each group throughout the study. The allocation process is as follows: as soon as each patient enters the study, his or her identification number is matched with the randomization list and the corresponding group is determined. To prevent bias, the person responsible for randomization and recording the data in a sealed envelope is independent of the treatment team. The only informed person is the attending physician responsible for the surgery. Each group includes 40 patients.
Blinding (investigator's opinion)
Single blinded
Blinding description
Patients will be informed about general issues in study groups. Patients who have entered the study after filling out the ethical consent form refer to the nurse. The nurse places a box with two folded papers, one A and the other B, in front of the patient. The patient selects a paper and gives it to the nurse. The nurse records it on the patient's form. Patients are randomly and blindly divided into two groups, A and, by a nurse.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics committee, sina hospital
Street address
Room 206, Ethics committee office, second floor, administrative building, sina hospital, imam khomeini street
City
Tehran
Province
Tehran
Postal code
1136746911
Approval date
2025-05-03, 1404/02/13
Ethics committee reference number
IR.TUMS.SINAHOSPITAL.REC.1404.071

Health conditions studied

1

Description of health condition studied
kidney stone disease
ICD-10 code
N00
ICD-10 code description
Acute nephritic syndrome

Primary outcomes

1

Description
urinary tract symptoms (pain, irritation, urinary frequency & urgency)
Timepoint
3 , 7 and 14 days after placement of double J stent
Method of measurement
Ureteral Symptom Stent Questionnaire

Secondary outcomes

1

Description
Biofilm formation
Timepoint
Days 3, 7, and 14 after placement of the Extra Double G stent
Method of measurement
Urine bacterial culture

2

Description
Analysis of mineral deposits
Timepoint
Days 3, 7, and 14 after placement of the Extra Double G stent
Method of measurement
FECal grading

Intervention groups

1

Description
Intervention group: In the intervention group, 40 patients will receive a double-loop double-J stent. A double-J stent is a stent with two loops extending outward from the midline of the kidney, designed at the suggestion of the Urology Center of Sina Hospital. Both the distal and proximal loops of this stent are positioned outward from the midline, whereas in standard stents, the proximal loop is positioned outward and the distal loop is positioned inward.
Category
Prevention

2

Description
Control group: 40 patients receive standard double-J stents. In standard stents, the proximal loop faces outward and the distal loop faces inward.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Dr.Mohammad Kazem Aghamir
Street address
Imam Khomeini st
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Ramin Kordi
Street address
Iran تهران، بلوار کشاورز، نبش خیابان قدس، سازمان مرکزی دانشگاه، طبقه ششم
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Dr Zahra Navi
Position
Researcher
Latest degree
Ph.D.
Other areas of specialty/work
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Head of Urology Research Center
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Demographic information anonymously
When the data will become available and for how long
One year after the results are published
To whom data/document is available
Researchers working in academic and scientific institutes, doctors, hospital surgeons
Under which criteria data/document could be used
Any analysis can be done with the consent of the main reserarcher
From where data/document is obtainable
Sina Hospital, Urology Research Centet,Head of Urology Research Center:Dr seyed mohammad kazem Aghamir
What processes are involved for a request to access data/document
After the review by the main executive and epidemiologist, while maintaining confidentiality, the information of the patients will be provided to the applicant
Comments