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Turning the tip of the stent upside down may ease urinary symptoms

Submission date
15/10/2024

Recruitment status
No longer recruiting

Registration date
22/10/2024

Overall study status
Completed

Last Edited
25/02/2025

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
This study aims to find out if changing the direction of a double-j stent placed in the ureter can reduce the uncomfortable urinary symptoms that patients often experience. The researchers want to see if turning the tip of the stent outward instead of inward makes a difference.

Who can participate?
Patients who have undergone a procedure called ureteroscopy for kidney or ureteral stones and have had a double-j stent inserted can participate in this study.

What does the study involve?
Participants will be divided into two groups based on the direction of their ureteral stent. They will fill out a questionnaire about their symptoms before and after the treatment. The researchers will compare the results to see if there is a difference between the two groups.

What are the possible benefits and risks of participating?
The possible benefit of participating is that it may help identify a better way to place stents that reduces urinary symptoms. The risks are minimal and are mainly related to the standard procedure of having a stent placed.

Where is the study run from?
The study is being conducted at Medical Park Gebze Hospital Urology Clinic (Turkey)

When is the study starting and how long is it expected to run for?
May 2023 to September 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr. Goksel Bayar, goxelle@yahoo.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Study information

Scientific Title
Reverse placement of a double J ureteral stent improve lower urinary tract symptoms

Study objectives
If we place the tip of the stent upside down, we can reduce contact with the bladder trigone. In this way, the patient's complaints can be reduced.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 01/06/2024, Istinye university local ethics committee (Hamidiye, Kâğıthane, İstanbul, 34408, Türkiye; +90 8502836000; info@istinye.edu.tr), ref: 24-120

Primary study design
Interventional

Study design
Prospective randomized controlled

Study type(s)
Quality of life, Treatment, Safety, Efficacy

Health condition(s) or problem(s) studied
Improve lower urinary tract symptoms on patients that inserted double-j stent

Interventions

At the end of ureteroscopy, double-j stent was inserted as normal in control group and reverse in study group. Follow-up duration was until removed stent from kidney about a month. Randomisation was performed online on website:https://clincalc.com/stats/samplesize.aspx)

Intervention Type
Procedure/Surgery

Primary outcome(s)
Ureteral stent symptoms questionnaire score before stent removal

Key secondary outcome(s)
Pain measured as use of painkiller or not, measured by interview before stent removal

Completion date
01/09/2024

Eligibility

Key inclusion criteria
Patient underwent ureteroscopy and inserted double-j stent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
116

Key exclusion criteria
1. Bilateral operation performed
2. Have previous lower urinary tract symptoms (etc. prostate hyperplasia, overactive bladder)
3. Pregnant

Date of first enrolment
05/06/2024

Date of final enrolment
05/08/2024

Locations

Countries of recruitment
Türkiye

Study participating centre
Gebze Medical Park Hospital
Guzellller mah
Kocaeli
Türkiye
41400

Sponsor information

Organisation
Gebze Medical Park Hospital

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/02/2025	25/02/2025	Yes	No