

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

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| Submission date 15/10/2024 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 22/10/2024 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| Last Edited 25/02/2025 | Condition category Urological and Genital Diseases | <input type="checkbox"/> 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

Contact name

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Additional identifiers**Clinical Trials Information System (CTIS)**

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

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

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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

Study design

Prospective randomized controlled

Primary study design

Interventional

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

Guzeller 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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |