

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

<b>Submission date</b> 15/10/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 22/10/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/02/2025	<b>Condition category</b> 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****EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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**

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](mailto:info@istinye.edu.tr)), ref: 24-120

**Study design**

Prospective randomized controlled

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Quality of life, Treatment, Safety, Efficacy

**Participant information sheet**

No participant information sheet available

**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 measure**

Ureteral stent symptoms questionnaire score before stent removal

**Secondary outcome measures**

Pain measured as use of painkiller or not, measured by interview before stent removal

**Overall study start date**

01/05/2023

**Completion date**

01/09/2024

**Eligibility****Key inclusion criteria**

Patient underwent ureteroscopy and inserted double-j stent

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Upper age limit**

65 Years

**Sex**

Both

**Target number of participants**

140

**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

Guzelller mah

Kocaeli

Türkiye

41400

## **Sponsor information**

**Organisation**

Gebze Medical Park Hospital

**Sponsor details**

Guzeller mah kavak cad

Kocaeli

Türkiye  
41400  
+90 (262) 675 75 75  
erol.turan@medicalpark.com.tr

**Sponsor type**

Hospital/treatment centre

**Website**

<https://www.medicalpark.com.tr/gebze-hastanesi/h-7>

## Funder(s)

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## Results and Publications

**Publication and dissemination plan**

Planned publication in a peer-reviewed journal

**Intention to publish date**

01/11/2024

**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?
<a href="#">Results article</a>		24/02/2025	25/02/2025	Yes	No