

# Comparative study of two interventional procedures for the treatment of kidney stones in order to ascertain which is the better technique

<b>Submission date</b> 02/02/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 16/02/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/09/2022	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

A kidney stone that blocks the ureter, the tube that connects your kidney to your bladder, can cause a kidney infection. This is because waste products are unable to pass the blockage, which may cause a build-up of bacteria.

An external ureteral catheter (a tube that collects urine from the kidney and passes it to a bag outside the body) and double J stent (a tube placed inside the ureter to hold it open and allow urine past the blockage) are both commonly used techniques to drain upper urinary passages in the treatment of kidney stones. We are comparing the outcomes of these two procedures in patients with kidney stones in order to identify a better technique for the management of kidney stones in terms of post-surgical stent-related symptoms.

### Who can participate?

Patients aged 18 - 70 years with kidney stones.

### What does the study involve?

Participants will be randomly allocated to receive an external catheter or double J stent.

### What are the possible benefits and risks of participating?

Possible benefit would be to choose a better technique with less complications in management of renal stones.

Possible risks include surgery related infections and bleeding .

### Where is the study run from?

Pakistan Atomic Energy General Hospital

### When is the study starting and how long is it expected to run for?

September 2019 to December 2020

Who is funding the study?  
Investigator initiated and funded

Who is the main contact?  
Dr Bilal Habib, rbilal14@yahoo.com

## Contact information

### Type(s)

Principal investigator

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## **Additional identifiers**

### **Protocol serial number**

PGHI-IRB(DMe)-RCD-06-002

## **Study information**

### **Scientific Title**

Which is the better technique in terms of postoperative stent-related complications? A comparative study of externalized ureteral catheter versus double-J stent on percutaneous nephrolithotomy

### **Study objectives**

To identify a better technique for the management of renal stones in terms of postoperative stent related symptoms.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 24/09/2019, Institutional Ethical Committee of PGHI (Faqr Aipee road, H 11/4, Islamabad, Pakistan; +92514434521; Pghiethics@outlook.com), ref: PGHI-IRB (DMe)-RCD-06-002

### **Study design**

Single center interventional double blinded randomized controlled trial

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Externalized ureteral catheter versus double-J stent on percutaneous nephrolithotomy

### **Interventions**

Enrolled patients were randomized by using the lottery method of randomization into two groups:

Group I (Double J stent placement)

Group II (Externalized ureteral catheter)

All the enrolled patients underwent the percutaneous nephrolithotomy (PCNL) procedure as per the standard protocol of our setting. In group I, the DJ stent was placed anterogradely under fluoroscopy. In group II, the EUC was left at the end of the procedure.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

Stent related symptoms measured using interview of patients/history taking at post operative Day 1, day 2 and week 2

### **Key secondary outcome(s)**

Measured using interview of patients/history taking at post operative Day 1, day 2 and week 2

1. Urinary leak
2. Fever
3. Analgesia requirement
4. Length of hospital stay

### **Completion date**

31/12/2020

## **Eligibility**

### **Key inclusion criteria**

1. Age 18-70 years
2. Cumulative stone diameter <4cm
3. Without ureteral obstruction
4. Single access site

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Upper age limit**

70 years

### **Sex**

All

### **Total final enrolment**

80

**Key exclusion criteria**

1. Bleeding disorders
2. Presence of significant residual calculi
3. Pyouria
4. Perforation of the renal collecting system
5. Severe intraoperative or post operative hemorrhage
6. Second look procedure necessity

**Date of first enrolment**

24/09/2019

**Date of final enrolment**

25/08/2020

**Locations****Countries of recruitment**

Pakistan

**Study participating centre**

**Pakistan Atomic Energy General Hospital**

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**Sponsor information****Organisation**

Pakistan Atomic Energy commission Hospital

**Funder(s)****Funder type**

Other

**Funder Name**

Investigator initiated and funded

# Results and Publications

## Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication

## IPD sharing plan summary

Published as a supplement to the results publication

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		08/03/2022	05/09/2022	Yes	No