

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

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

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

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 measure

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

Secondary outcome measures

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

Overall study start date

01/09/2019

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

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Both

Target number of participants

80

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

Department of Urology

Faqir Apee Road H 11/4 Islamabad

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Sponsor information

Organisation

Pakistan Atomic Energy commission Hospital

Sponsor details

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Sponsor type

Hospital/treatment centre

Funder(s)**Funder type**

Other

Funder Name

Investigator initiated and funded

Results and Publications**Publication and dissemination plan**

Planned publication in a high impact peer-reviewed journal

Intention to publish date

01/03/2022

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?
Results article		08/03/2022	05/09/2022	Yes	No