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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

Registration date
16/02/2022

Overall study status
Completed

Last Edited
05/09/2022

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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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 (Faqir Aipee road, H 11/4, Islamabad, Pakistan; +92514434521; Pghiethics@outlook.com), ref: PGHI-IRB (DMe)-RCD-06-002

Primary study design
Interventional

Study design
Single center interventional double blinded randomized controlled trial

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
Department of Urology
Faqir Apee Road H 11/4 Islamabad
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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?
Results article		08/03/2022	05/09/2022	Yes	No