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Does performing percutaneous nephrolithotomy in the split-leg modified lateral position reduce the overall operative time compared to the standard prone position?

Submission date
03/04/2020

Recruitment status
No longer recruiting

Registration date
06/04/2020

Overall study status
Completed

Last Edited
06/04/2020

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Since percutaneous nephrolithotomy (PNL), an operation to treat kidney stones was initially described, the prone position (PP) has been the most commonly used position for the operation. However, this position does have some drawbacks. It can represent a challenge for giving anesthesia and therefore waste considerable time. It also carries a substantial risk to obese patients and patients with respiratory difficulties.

In 2011 the split-leg MLP (SL-MLP) position was introduced and was praised for its benefits for patients and surgeons. This position gives the advantage of access to the whole kidney. Carrying out the operation in this position has been shown to be both feasible and safe, but so far there has not been research into whether this position gives better outcomes compared to the standard prone position.

This study aims to compare PNL procedures performed in the SL-MLP position with those in the prone position as a standard control. The procedures will be compared in terms of operation duration and patient outcomes.

Who can participate?
Patients who require percutaneous nephrolithotomy (PNL) operation for renal stones

What does the study involve?
Before their scheduled operation, participants will have a full medical history taking, physical examination, and blood and urine samples taken for laboratory testing. They will also have an ultrasound scan, CT scan and x-ray of their abdomen.

Participants will either receive their scheduled PNL operation in the prone or SL-MLP position.

Following their operation, participants will repeat the testing prior to the operation. They will have blood samples taken after one day, have an ultrasound scan and x-ray after 2 days, and have a CT scan after two weeks.

What are the possible benefits and risks of participating?
This study will help to identify the best positioning technique with short operation time for PNL procedures for future patients.

Performing PNL in SL-MLP has no additional risk to study participant. The participant may get benefit from the expected short operative time and the inclusion of additional procedures, if needed, without changing position. All PNL complications will be managed at our institution.

The research will be explained in detail to the patients before inclusion in the study. The patients will sign an informed written consent before enrollment. Extreme care will be taken during the research-related procedures. It will be made clear that the subject has the full right to withdraw from the study at any time.

Where is the study run from?
Al-Azhar University Hospital (Egypt)

When is the study starting and how long is it expected to run for?
From July 2017 to October 2019

Who is funding the study?
This study is investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Uro_Azhar_12_017

Study information

Scientific Title
Split-Leg Modified Lateral versus Prone Position in Percutaneous Nephrolithotomy: A Prospective, Randomized Trial

Study objectives
Performing percutaneous nephrolithotomy in split-leg modified lateral position may reduce the overall operative time compared to the standard prone position.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/07/2017, the Research Ethics Committee of the Urology Department, Al-Azhar University (Al-Azhar University, Cairo, 11633 Egypt; +2025107222; urologydepartment@azhar.edu.eg), ref: Uro_Azhar_12_017.

Study design
Single-center, unblinded, two-arm (1:1), randomized controlled interventional study

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 participant information sheet. Abul-fotouh Ahmed, abulfotouhahmed@yahoo.com, +201001066756

Health condition(s) or problem(s) studied
Renal stones requiring percutaneous nephrolithotomy

Interventions
According to the position technique during percutaneous nephrolithotomy (PNL), the study participants will be randomly assigned to one of the two treatment groups. The first group: in which the PNL procedures will be performed in the split-leg modified lateral position. The second group: in which the PNL procedures will be performed in the standard prone position. Stratified blocked randomization (1:1 ratio) will be performed according to the pre-determined Guy's stone score and each grade with its own list to keep the groups closely balanced.

Pre-operatively all patients will be evaluated by full medical history taking, physical examination, and laboratory investigations in the form of complete urine analysis with urine culture, blood chemistry tests including blood urea, serum creatinine, liver function tests, coagulation profile and complete blood cell count (CBC). The pre-operative imaging studies are plain abdominal X-ray for kidney, ureters and urinary bladders (KUB), abdominal ultrasonography, and abdominal non-contrast Computed Tomography (NCCT).

All patients will be evaluated by CBC on a postoperative day one, plain X-ray KUB and abdominal ultrasonography on the postoperative day two and abdominal NCCT two weeks after PNL

Intervention Type
Procedure/Surgery

Primary outcome measure
Overall operative time, defined as the time from induction of anesthesia to the placement of nephrostomy tube in minutes

Secondary outcome measures
1. Track formation time defined as the time from pelvicalyceal puncture till Amplatz sheath fixation in minutes
2. Fluoroscopy time defined as the time of fluoroscopic x-ray exposure during all steps of the procedure in minutes
3. The stone-free rate (SFR) measured using abdominal NCCT at 2 weeks postoperatively. Stone free status is defined as no visualized stone or residual fragments <3 mm on abdominal NCCT.
4. Re-treatment rate measured from patient notes at 2 years. Defined as the need for more than one session of PNL procedure to treat the renal stone during the trial period.
5. Hospitalization duration in days assessed from the patient notes at discharge
6. Incidence of bleeding and other perioperative complications assessed from patient notes at discharge. PNL complications will be classified and graded according to the modified Clavien classification system

Overall study start date
15/07/2017

Completion date
20/10/2019

Eligibility

Key inclusion criteria

Requires percutaneous nephrolithotomy (PNL) intervention for renal stones

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
130 (65 in each group) adult patients, requiring PNL intervention for renal stones.

Key exclusion criteria
1. Complete staghorn stone
2. Pregnancy
3. Uncorrectable coagulation disorders
4. Urinary tract obstruction distal to the stone
5. Active urinary tract infection (UTI)
6. Renal anomalies
7. Severe orthopaedic deformity

Date of first enrolment
07/11/2017

Date of final enrolment
01/10/2019

Locations

Countries of recruitment
Egypt

Study participating centre
Al-Azhar University Hospital
Cairo
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Sponsor information

Organisation
Al Azhar University

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Sponsor type
Hospital/treatment centre

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ROR
https://ror.org/05fnp1145

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
01/04/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Not provided at time of registration