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Comparison of the complications between the papillary and infundibular access to the cacyceal system of the kidney during percutaneous nephtrolithotomy.

Submission date
12/06/2016

Recruitment status
No longer recruiting

Registration date
23/07/2016

Overall study status
Completed

Last Edited
23/10/2018

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Renal (or kidney) stones are stones that can develop in the kidneys. They are quite common. Many go undetected and are passed out painlessly in the urine. However, they can cause a blockage in the urinary system. Such blockages can cause severe pain. Large kidney stones can be removed by a surgical procedure called percutaneous nephrolithotomy (PCNL). This involves using a thin telescopic instrument called a nephroscope which is passed through the kidney to either pull out the stone r break it into smaller pieces using a laser or pneumatic energy. The procedure requires precise puncture with a needle of the collecting system of the kidney in specific positions which are called as “papillae”. These sites are considered to less prone to bleeding either during or after the surgery. However, there is evidence to suggest that there is no significant bleeding risk if the puncture is made in other positions of the collecting system such as the “infundibulum”, a site that allows easier approach is easier movement of the instrument. This study is looking at whether this is the case.

Who can participate?
Patients with large renal stones.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 undergo percutaneous nephrolithotomy with access to the papilla. Those in group 2 undergo the surgery with
access to the infundibulum. All participants are monitored for complications after surgery and whether they need any blood transfusions. They are followed up for three months after surgery.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University Hospital of Patras (Greece)

When is the study starting and how long is it expected to run for?
June 2015 to June 2017

Who is funding the study?
University of Patras (Greece)

Who is the main contact?
Professor Evangelos Liatsikos

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11393/16-6-2015

Study information

Scientific Title
Randomized trial comparing the surgical outcome and morbidity of the accesses to fornix-papilla to the accesses to the infundibulum of the calyx of the kidney during percutaneous nephtrolithotomy.

Study objectives
The traditional practice of percutaneous nephtrolithotomy uses an access for the pelvicalyceal system through the papilla-fornix of the renal calyx. The access through the infundibulum of the renal calyx is considered as prone to bleeding is performed only in difficult cases in which the

papillary access is not possible. The clinical experience of our institution shows that there is no difference in complication rates and morbidity between the papillary and the infundibular access. The current randomized study aims to provide high quality data on the comparison of the above approaches.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scientific Board of the University Hospital of Patras, 6th Hygeonomic Region of Greece, 27/05 /2015, ref: 11393/16-6-2015

Study design
Randomised 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. An informed consent form is available in Greek.

Health condition(s) or problem(s) studied
Lithiasis of the urinary tract. Large stone in the renal pelvicalyceal system.

Interventions
Participants are randomly allocated to one of two groups:

Group 1: Undergo percutaneous nephtrolithotomy with access and tract dilation to the papilla of the desired calyx (control)
Group 2: Undergo percutaneous nephtrolithotomy with access and tract dilation to the infudibulum of the desired calyx (intervention)

The intervention performed in all patients is the percutaneous nephrolithotomy (PCNL) which is performed for the management of large renal stones. PCNL is performed with the patient in prone position after the patient is intubated and a ureteral catheter has been inserted to pelvicalcyceal system of the kindey that is going to be treated. Under fluoroscopic guidance the desired renal calyx puncture is made with the use of a 18G needle. The common practice is to puncture the fornix-papilla of the desired calyx (control arm). The procedure can also be performed by puncturing the infundibulum of the desired renal calyx (intervention). The rest of the procedure is performed by inserting appropriate guidewires and dilating the tract to the pelvicalyceal system at a diameter of 30Fr with the use of Amplatz dilators or Balloon dilator. A

nephroscope is inserted and the stones to be treated and are detected and removed with the use of clamp or ultrasound lithotripter. At the end of the procedure a Malecot nephrostomy tube is left in place.

The patients are discharged on the 2-3 postoperative day based on the presence of clear urine in the Malecot tube. An KUB x-ray or KUB CT scan are performed for the confirmation of the stone free status on the discharge day after the removal of the Malecot catheter. Blood and serum examinations take place during the hospitalization of the patients.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. The hemoglobin drop on the first postoperative day and discharge day
2. Need for transfusion during the first postoperative month

Secondary outcome measures
1. Operative time
2. Number of accesses performed
3. Stone free rate (at discharge and 3 months)
4. Complications rate (during the 4 weeks and 3 months postoperatively)
5. Hospitalization

Overall study start date
17/06/2015

Completion date
16/06/2017

Eligibility

Key inclusion criteria
Renal stones >2cm in maximal diameter with indication for percutaneous nephrolithotomy.

Participant type(s)
Patient

Age group
All

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Single kidney
2. Ureteral stone in the same system
3. Stone in diverticulum

4. Concomitant urinary infection
5. Congenital anomalies of the urinary tract
6. Skeletal anomalies

Date of first enrolment
17/06/2015

Date of final enrolment
16/06/2017

Locations

Countries of recruitment
Greece

Study participating centre
University Hospital of Patras
Department of Urology (4th floor)
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Sponsor information

Organisation
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Sponsor type
Other

ROR
https://ror.org/03c3d1v10

Funder(s)

Funder type
University/education

Funder Name
University of Patras

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Greece

Results and Publications

Publication and dissemination plan
The results of the study will be published in an international journal as soon as they are available.

Intention to publish date
31/10/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2017		Yes	No
Basic results		23/10/2018	23/10/2018	No	No