

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

<b>Submission date</b> 12/06/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/07/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 23/10/2018	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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 or 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 be 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 and 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

**Contact name**  
Prof Evangelos Liatsikos

**Contact details**  
Department of Urology (4th floor)  
University Hospital of Patras  
Rion  
Patras  
Greece  
26504

## 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 nephrolithotomy.

**Study objectives**  
The traditional practice of percutaneous nephrolithotomy 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 nephrolithotomy with access and tract dilation to the papilla of the desired calyx (control)

Group 2: Undergo percutaneous nephrolithotomy with access and tract dilation to the infundibulum 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 pelvicalyceal system of the kidney 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)

Rion

Patras

Greece

26504

## **Sponsor information**

**Organisation**

Evangelos Liatsikos

**Sponsor details**

Department of Urology (4th floor)

University Hospital of Patras

Rion

Patras

Greece

26504

**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?
<a href="#">Results article</a>	results	01/04/2017		Yes	No
<a href="#">Basic results</a>		23/10/2018	23/10/2018	No	No