

The role of surgical treatment on lower pole renal stones

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| Submission date 10/01/2017 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| | | <input type="checkbox"/> Protocol |
| Registration date 16/02/2017 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| Last Edited 03/04/2024 | Condition category Urological and Genital Diseases | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Kidney stones are hard stones that form in the kidneys. If a stone blocks part of the urinary system, such as the ureter (the tube connecting the kidney to the bladder) or the urethra (the tube urine passes through on its way out of the body), this can cause severe pain. The aim of this study is to compare three treatments for kidney stones: Retrograde IntraRenal Surgery (RIRS), Shock Wave Lithotripsy (SWL) and Percutaneous Lithotripsy (PCNL). RIRS involves passing a long, thin telescope (ureteroscopy) through the urethra, into the bladder and up into the ureter, where the stone is broken up using a laser. SWL involves using ultrasound shock waves to break the stone into smaller pieces. PCNL involves passing a thin telescopic instrument (nephroscope) through a small incision (cut) into the kidney, and the stone is broken up using a laser.

Who can participate?

Patients aged between 18 and 75 with a single lower pole kidney stone with a diameter of 1 to 2 cm

What does the study involve?

Participants are randomly allocated to undergo either SWL, RIRS or PCNL, as described above. Participants undergo an x-ray or ultrasound scan after 10 days and a CT scan after 3 months to find out whether they are now stone free. Any complications of the procedures are recorded during hospitalization and at 3 months follow-up.

What are the possible benefits and risks of participating?

Participants benefit from treatment with brand new devices.

Where is the study run from?

1. Humanitas Mater Domini (Italy)
2. San Paolo Hospital (Italy)
3. Federico II Napoli (Italy)
4. Seconda Univ. Napoli (Italy)
5. Graz General Hospital (Austria)
6. Lomonosov Univ Moscow (Russia)
7. King's College Hospital (UK)

When is the study starting and how long is it expected to run for?
January 2010 to December 2014

Who is funding the study?
European Association of Urology (Netherlands)

Who is the main contact?
Giorgio Bozzini

Contact information

Type(s)
Scientific

Contact name
Mr Giorgio Bozzini

Contact details
via Gerenzano 2
Castellanza
Italy
21053

Additional identifiers

Clinical Trials Information System (CTIS)
2009-001328-14

Protocol serial number
77/gb/2009

Study information

Scientific Title
A prospective randomized comparison among shock wave lithotripsy, percutaneous lithotripsy and retrograde intrarenal surgery for lower calyceal stones less than 2 cm: a multicenter experience

Study objectives
To prospectively evaluate the efficacy and safety of Retrograde IntraRenal Surgery (RIRS), Shock Wave Lithotripsy (SWL) and Percutaneous Lithotripsy (PCNL) for lower calyceal stones sized 1-2 cm.

Ethics approval required
Old ethics approval format

Ethics approval(s)
ASL Milano 2, 12/03/2009, ref: 2009/2388/DU

Study design

Multicenter randomized unblinded clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Renal lower calyceal stones

Interventions

Patients will be randomized into three groups:

Group A: SWL

Group B: RIRS

Group C: PCNL

The randomization allocation sequence will be produced with the online free Random Allocation Software (M. Saghaj, MD). The principal investigator for each center will enroll and assign participants to groups. The randomization will be stratified by center. Each center will use their own equipment to perform treatments, but the procedures will be standardized and were supervised by an experienced surgeon in the field of stone management.

SWL will be performed with ultrasound or x-ray guided targeting of the stone with a frequency of 100 impulses/min and a maximum of 2500 shock waves (SW) per session. Patients will be observed for at least two hours after the SWL and then discharged as an outpatient procedure.

RIRS will be performed with a flexible ureteroscope and a 30 W Holmium YAG Laser device. Before the sheath insertion, an ureteric dilatation will be performed when required. Bigger fragments will be removed with a stone retrieval basket. After the procedure a double J stent will be inserted in all patients and its removal will be planned after 4 weeks if the patient will be stone free.

PCNL will be performed with a rigid nephroscope 20.8 to 24 Fr. and a 30 W Holmium YAG Laser device. PCNL will be performed with the patient either in prone or modified supine position according to the operator's preference. The kidney puncture will be performed under fluoroscopic and/or US guidance. Calyx will be cleaned removing bigger fragments with a stone retrieval basket. Each patient will have a nephrostomy tube placement after the procedure removed after two days if urine is clear.

A stone analysis will be performed in all cases, when fragments available. Patients affected by uric acid stones will be treated with oral chemolysis in order to reach the stone free status.

Patients will be evaluated with kidney-ureter-bladder (KUB) radiography after 10 days (ultrasonography for uric acid stones) and a CT scan after 3 months, unless residual fragments will be present after the first treatment session.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Stone-free rate (SFR), defined as a negative CT scan or an asymptomatic patient with stone fragments less than 3 mm and a negative urine culture, measured at 3 months

Key secondary outcome(s)

Peri- and post-operative complications of procedures, classified using the validated Dindo-modified Clavien System, during the hospitalization and until 3 months

Completion date

31/12/2014

Eligibility**Key inclusion criteria**

1. Consecutive patients with a single LP stone with a diameter of 1 to 2 cm as measured at CT scan, that received the indication of active removal according to EAU Guidelines
2. Age between 18 and 75 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Presence of coagulation disorders
2. Age under 18 or over 75 years
3. Presence of acute infection (fever more than 38° C or total leucocyte count more than 15000 /dl)
4. Presence of solitary kidney
5. Coexisting ureteric disease (tumour or stricture)
6. Pregnancy
7. Presence of cardiovascular or pulmonary comorbidities
8. Multiple stones
9. Steep infundibolar-pelvic angle (< 30°)
10. Longer calyx more than 10 mm
11. Narrow infundibulum (less than 5 mm) as demonstrated by contrast enhanced CT
12. Patients who refuse to give consent to the study

Date of first enrolment

01/01/2010

Date of final enrolment

30/06/2014

Locations**Countries of recruitment**

United Kingdom

England

Austria

Italy

Russian Federation

Study participating centre

Humanitas Mater Domini

Castellanza

Italy

21053

Study participating centre

San Paolo Hospital

Milan

Italy

20100

Study participating centre

Federico II Napoli

Naples

Italy

80121

Study participating centre

Seconda Univ. Napoli

Naples

Italy

80121

Study participating centre

Graz General Hospital

Graz
Austria
8020

Study participating centre**Lomonosov Univ Moscow**

Moscow
Russian Federation
101

Study participating centre**King's College Hospital**

London
United Kingdom
SE5 9RS

Sponsor information**Organisation**

Humanitas Mater Domini - Castellanza

ROR

<https://ror.org/03n1tvb36>

Funder(s)**Funder type**

Research organisation

Funder Name

European Association of Urology

Alternative Name(s)

EAU

Funding Body Type

Private sector organisation

Funding Body Subtype

Associations and societies (private and public)

Location

Netherlands

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary

Other

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|------------------------------------|--|--------------|------------|----------------|-----------------|
| Results article | results | 01/12/2017 | | Yes | No |
| Results article | | 31/07/2021 | 15/03/2023 | Yes | No |
| Results article | | 23/10/2021 | 15/03/2023 | Yes | No |
| Other publications | A proposed mathematical model to help preoperative planning between RIRS and MiniPerc for renal stones | 02/04/2024 | 03/04/2024 | Yes | No |