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The role of surgical treatment on lower pole renal stones

Submission date	Recruitment status	[_] Prospectively registered
10/01/2017	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/02/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/04/2024	Urological and Genital Diseases	

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 (ureteroscope) 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

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Additional identifiers

EudraCT/CTIS number
2009-001328-14

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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. Saghaei, 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 measure
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

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

Overall study start date
01/01/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
176 per arm

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
Austria

England

Italy

Russian Federation

United Kingdom

Study participating centre
Humanitas Mater Domini
Castellanza
Italy
21053

Study participating centre
San Paolo Hospital
Milan
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Study participating centre
Federico II Napoli
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Study participating centre
Seconda Univ. Napoli
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Study participating centre
Graz General Hospital
Graz
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8020

Study participating centre
Lomonosov Univ Moscow
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101

Study participating centre
King's College Hospital
London
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SE5 9RS

Sponsor information

Organisation
Humanitas Mater Domini - Castellanza

Sponsor details

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Castellanza
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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Planned publication in a high-impact peer review journal after one year of the end of the study

Intention to publish date
01/06/2015

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