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Kidney stone laser treatment via miniaturised telescopes through the back versus telescopes via the urinary tract in an Indian population

Submission date
12/04/2020

Recruitment status
No longer recruiting

Registration date
12/05/2020

Overall study status
Completed

Last Edited
03/02/2022

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
Waste products in the blood can occasionally form crystals that collect inside the kidneys.Over time, the crystals may build up to form a hard stone-like lump. Kidney stones are usually found in the kidneys or in the ureter, the tube that connects the kidneys to your bladder. They can be extremely painful, and can lead to kidney infections or the kidney not working properly if left untreated.
The aim of this study is to compare kidney stone laser treatment via miniaturised telescopes through the back versus telescopes via the urinary tract in an Indian population.
Who can participate?
Patients aged 16 years and above with 10 – 30 mm kidney stone(s).

What does the study involve?
Participants will be randomly allocated to receive ultra-mini percutaneous nephrolithotomy (UMP) or Retrograde Internal Surgery (RIRS) for the removal of kidney stones. Participants will be followed-up at one month.

What are the possible benefits and risks of participating?
The benefits of the mini key hole operation was to avoid the need for a second procedure to remove the stent which is needed for the surgical treatment of the kidney stones via the telescope into the urinary tract from below. The other advantages were the ability to remove the maximum stone burden with a single procedure and which is not uncommon with the operation through the urinary tract from below. This operation is less invasive than the standard operation which involves a bigger size of the telescope. The risks were more or less similar in either of the procedure are blood in the urine and urine infection and which extremely rarely can be serious. The risks of the residual stone following the procedures is another factor to consider in either of them.

Where is the study run from?
Samved Hospital (India)

When is the study starting and how long is it expected to run for?
December 2013 to December 2015

Who is funding the study?
Samved Hospital (India)

Who is the main contact?
Ramandeep Chalokia, rchalokia@yahoo.com
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
UMP001

Study information

Scientific Title
Ultra mini-percutaneous nephrolithotomy versus retrograde intrarenal surgery in the treatment of 10-30 mm calculi: A randomised controlled trial

Study objectives
The aims are to investigate the efficacy, cost and safety of ultra mini-percutaneous nephrolithotomy (UMP) versus retrograde intrarenal surgery (RIRS) in renal calculi between 10 - 30mm

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/07/2014, Ethics Committee Samved Hospital (2nd Floor Samved Hospital, Near Stadium Circle, Ahmedabad, Gujarat, India, 380009; +91 (0)7926431616; drrushimishra@gmail.com), ref: n/a

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Renal calculi

Interventions
The patients will be randomised using block randomisation software into either the UMP or RIRS group with a ratio of 2:1. Block randomisation design will be used to reduce bias and achieve balance. Block sizes of 6 will be used. The patients will be informed of the procedure after randomisation.

The duration of surgery will be measured (from the visualisation of the stone) and any equipment used during the procedure will be noted to calculate the total cost of the intervention. The requirement and duration of a nephrostomy, DJ stent, and indwelling urinary catheter will be recorded. At the end of each procedure, it will be essential to record the number of patients that will be stone free or had any residual fragments present. Patients will be identified as being stone-free if no identifiable stones can be verified on direct visualization /fluoroscopic. Residual fragments will be defined as those >4 mm.

Deterioration in renal function and bleeding will be assessed by comparing pre-operative haemoglobin (Hb) and creatinine levels with those on the first postoperative day. The need and duration of post-operative opioid Intramuscular/Intravenous analgesia will be recorded, and patients with prolonged pain will be identified. Prolonged pain will be defined as greater than two days in duration requiring anti-spasmodic medication. Post-operative complications will be recognised and classified as per the Clavien-Dindo grading system. The length of hospital stay for each patient and the number of patients that will be required to return (e.g. stent removal) will be recorded. Following discharge, patients will be invited back in one month for a follow-up low dose NCCT scan to identify the presence of residual fragments. Residual fragments will be defined as any calcification ≥ 4 mm present on the NCCT in the kidneys, ureters or bladder.

Intervention Type
Procedure/Surgery

Primary outcome measure
Presence of residual fragments at one month after surgery measured using fluoroscopy

Secondary outcome measures
1. Duration of surgery (minutes) measured using a clock
2. Stone size before surgery measured using fluoroscopy
3. Stent requirement during surgery (yes or no) and duration of stent dwelling measured at one month follow up appointment
4. Nephrostomy requirement and duration
5. Cost of procedure measured using duration and equipment used at the time of surgery
6. Blood Hb and creatinine measured using blood test at baseline and one day post-operatively
7. Duration of hospital stay (hours)
8. Complications and adverse events measured using the Clavien-Dindo Classification of Surgical

Complications
9. Presence of haematuria measured by urine analysis during hospital stay

Overall study start date
12/12/2013

Completion date
31/12/2015

Eligibility

Key inclusion criteria
1. Age > 16 years
2. 10 - 30mm renal calculi of any position with no history of bleeding diathesis

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
150

Total final enrolment
144

Key exclusion criteria
1. Abnormal renal or musculoskeletal anatomy
2. Receiving anticoagulants
3. High anaesthetic risk

Date of first enrolment
01/07/2014

Date of final enrolment
30/06/2015

Locations

Countries of recruitment
India

Study participating centre

Samved Hospital
Near Stadium Circle
Navrangpura
Ahmedabad
India
380009

Sponsor information

Organisation
Samved Hospital

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.samvedurology.com

ROR
https://ror.org/04esbsa15

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Samved Hospital

Results and Publications

Publication and dissemination plan
European Urology or another reputed journal.

Intention to publish date
12/05/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available upon request from Dr Janak Desai drjanakddesai@gmail.com
The data will be available after peer review publication for meta-analysis. Data will be anonymized. There was no specific patient consent for disclosure of data for metanalysis.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		02/02/2022	03/02/2022	Yes	No