ISRCTN13835301 https://doi.org/10.1186/ISRCTN13835301

Treatment of complex renal calculi

Submission date	Recruitment status	[_] Prospectively registered
15/08/2025	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/08/2025	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/08/2025	Urological and Genital Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Complex renal calculi is a common type of urinary calculi, which is difficult to treat and has a high probability of recurrence. The characteristics of rigid mirrors determine that there will inevitably be blind spots in the treatment of multiple renal stones and staghorn stones,resulting in serious consequences such as bleeding and renal parenchymal injury.RIRS has the advantages of less trauma, less bleeding, flexible bending of the end, and rapid recovery of damage caused by non-lens prying when entering the renal pelvis and calyces, which makes up for the shortcomings of rigid endoscopybut is complex operation.Percutaneous disposable electronic soft lens combined with percutaneous hard lens in the treatment of large renal load calculi has some advantages that flexible ureteroscope does not have. There are few related studies on it, and its clinical efficacy still needs to be further explored. This study is to investigate the clinical efficacy of single-channel percutaneous nephrolithotomy combined with disposable electronic soft lens in the treatment of complex renal calculi, and further explore the advantages and disadvantages and safety of this combined procedure for clinical reference.

Who can participate?
Patients with complex renal calculi.There were 13 males and 7 females in the observation group, with an average age of 45.80 ± 5.51 years and an average stone size of 3.44 ± 0.32 cm. There were 10 males and 10 females in the control group, with an average age of 46.25 ± 4.25 years and an average stone size of 3.43 ± 0.29 cm.

What does the study involve?
The observation group was treated with percutaneous renal single-channel disposable electronic soft lens combined with percutaneous nephroscopy, while the control group was treated with traditional single percutaneous nephroscopy.

What are the possible benefits and risks of participating?
The percutaneous disposable electronic soft lens combined with percutaneous hard lens used in this study has some advantages that the flexible ureteroscope does not have. It has higher resolution and clarity, and is not easy to cause renal parenchymal damage. Therefore, it can further shorten the operation time and reduce the bleeding rate.Although the situation has improved, there is still a risk of residual stones.

Where is the study run from?
This study was conducted at Hebei Yanda Hospital (China)

When is the study starting and how long is it expected to run for?
August 2023 to May 2025

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Yunbo Yang, Yangyunbo1266@163.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Clinical observation of single channel percutaneous nephrolithotomy combined with disposable electronic soft lens in the treatment of complex renal calculi

Study objectives

Percutaneous disposable electronic soft lens combined with percutaneous hard lens in the treatment of large renal load calculi has some advantages that flexible ureteroscope does not have. To explore the clinical efficacy of single-channel percutaneous nephrolithotomy combined with disposable electronic soft lens in the treatment of complex renal calculi, and further explore the advantages and disadvantages and safety of this combined procedure.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 12/05/2025, The Ethics Committee of Hebei Yanda Hospital (Sipulan Road, Yanjiao Development Zone, Sanhe City, 065000, China; +86-03163306666; ZJX_yandadoc@21cn.com), ref: Ethical Approval (Sci) No. 2025-05-009

Study design
Single-centre non randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Treatment of patients with complex kidney stones

Interventions
The patients are divided into observation group and control group by voluntary admission in advance. The observation group is treated with percutaneous renal single-channel disposable electronic soft lens combined with percutaneous nephroscopy; the control group is treated with traditional single percutaneous nephroscopy.
Total treatment time: preoperative to discharge, followed up for 3 months after surgery

Intervention Type
Procedure/Surgery

Primary outcome(s)
Stone clearance rate is measured using non-contrast computed tomography (CT) at 24 hours post-procedure

Key secondary outcome(s))
1. Stone clearance rate is measured using non-contrast computed tomography (CT) at 3 months post-operation
2. Operation time is measured using intraoperative surgical records at the time of surgery
3. Intraoperative blood loss is measured using surgical suction volume and gauze weight at the time of surgery
4. Hospitalization time is measured using patient discharge records from admission to discharge
5. Postoperative complications are measured using the Clavien-Dindo classification at ...
6. Quality of life is measured using the Generic Quality of Life Inventory-74 (GQOLI-74) at baseline and 1 month post-surgery
7. Inflammatory response is measured using serum C-reactive protein (CRP) levels at 24 hours

before surgery (T0), end of anesthesia (T1), 2 hours after surgery (T2), 12 hours after surgery (T3), 24 hours after surgery (T4), and 48 hours after surgery (T5)
8. Renal function is measured using serum cystatin C levels at baseline (before surgery), 2 hours after surgery, 12 hours after surgery, 24 hours after surgery, 48 hours after surgery, and 72 hours after surgery

Completion date
30/05/2025

Eligibility

Key inclusion criteria
1. Patients diagnosed with complex renal calculi combined with medical history, signs and imaging findings
2. All patients with preoperative urinary tract infection received anti-infective treatment and were well controlled
3. Patients with abnormal blood pressure, blood glucose and electrolyte before operation returned to normal and maintained stable after active treatment by doctors
4. Patients with preoperative renal insufficiency or severe hydronephrosis had undergone one-stage nephrostomy
5. The patients were able to accept the hospitalization expenses of the double-mirror combination, and the willingness to operate was strong. All patients signed the informed consent
6. The case data were complete and the examination was perfect

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
39 years

Upper age limit
55 years

Sex
All

Total final enrolment
40

Key exclusion criteria
1. There were systemic hemorrhagic diseases, and the coagulation function had not been corrected
2. Long-term use of anticoagulant drugs such as aspirin, warfarin, preoperative non withdrawal

for more than 1 week
3. With severe heart and lung disease, can not tolerate surgery and anesthesia
4. Renal malignant tumor, renal tuberculosis, pelvic ectopic kidney, polycystic kidney and severe renal prolapse were found before operation
5. The presence of severe joint or spinal deformity affects the placement of surgical position
6. Extremely obese, the skin-kidney distance value was too large, affecting the establishment of percutaneous renal working channel
7. Pregnant patients

Date of first enrolment
01/09/2023

Date of final enrolment
30/09/2024

Locations

Countries of recruitment
China

Study participating centre
Hebei Yanda Hospital
Sanhe City
China
065000

Sponsor information

Organisation
Hebei Yanda Hospital

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from Dr.Yunbo Yang
email: Yangyunbo1266@163.com

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes