Study Protocol

Title: A Multicenter, Randomized Controlled Trial Comparing Retrograde Intrarenal Surgery (RIRS) Using Tip-Flexible Suction Access Sheath with Standard Percutaneous Nephrolithotomy (PCNL) for the Treatment of 2-3 cm Unilateral Renal Stones

NCT Number: NCT00000000 (To be updated after registration approval)

Document Date: May 15, 2025

Study Protocol (Version X2.0 / April 8, 2025)

Title:
A Multicenter, Randomized Controlled Trial Comparing Retrograde Intrarenal Surgery (RIRS) Using Tip-Flexible Suction Ureteral Access Sheath (TFS-UAS) with Standard Percutaneous Nephrolithotomy (PCNL) for the Treatment of 2-3 cm Unilateral Renal Stones

Protocol ID: 20250408
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Study Period: April 2025 - June 2026

1. Background
Ureteroscopy (RIRS), percutaneous nephrolithotomy (PCNL), and extracorporeal shock wave lithotripsy are standard minimally invasive treatments for renal stones. In recent years, the use of RIRS has increased due to its flexibility, reduced trauma, and repeatability. To further improve outcomes, a new tip-flexible suction ureteral access sheath (TFS-UAS) has been developed. This sheath has a soft, bendable tip (~10 cm) and integrates continuous suction to reduce intrarenal pressure, enhance stone clearance, and improve visualization.

While both RIRS and PCNL are recommended for renal stones of 2-3 cm in diameter, there is limited prospective comparative evidence between TFS-UAS-assisted RIRS and standard PCNL. This study addresses this gap.

2. Objectives
To compare the clinical efficacy and safety of tip-flexible suction sheath-assisted RIRS and standard PCNL in the management of 2-3 cm unilateral renal stones.

3. Study Design
A prospective, multicenter, randomized controlled trial.

Population: Adults aged 18-80 with unilateral renal stones measuring 2-3 cm, eligible for surgical intervention.
Sample Size Calculation: Assuming 85% SFR for RIRS and 95% for PCNL, with alpha=0.05 and power=0.80, the minimum sample size per group is 140. Allowing for 10% dropout, each group will include at least 154 patients; total n=308.
Randomization: Block randomization will be used to allocate patients into either the RIRS group or PCNL group.
Blinding: Open-label.

4. Eligibility Criteria

Inclusion Criteria
1. Age 18-80 years
2. ASA physical status I-III
3. CT-confirmed unilateral renal stones measuring 2-3 cm
4. Signed informed consent

Exclusion Criteria
1. Anatomical urinary tract anomalies (e.g., horseshoe kidney, ileal conduit)
2. Uncontrolled urinary tract infection
3. Absolute contraindications to RIRS or PCNL
4. Inability to understand or comply with study procedures

5. Interventions

RIRS Group (Experimental):
- Under general anesthesia, a semirigid ureteroscope is used to assess the ureter.
- A TFS-UAS (F10 or F12.5) is inserted into the renal pelvis under guidewire.
- Flexible ureteroscope with irrigation and suction is used.
- Holmium laser (200 um) is applied for lithotripsy.
- Stone fragments are evacuated via suction or extracted with a basket.
- A double-J stent is placed postoperatively.

PCNL Group (Control):
- Under general anesthesia, ureteral catheter is placed and patient is positioned prone.
- Percutaneous access is established under ultrasound guidance.
- Tract dilation up to F22, nephroscope introduced.
- Holmium laser (550 um) used for stone fragmentation.
- Double-J stent and nephrostomy tube placed postoperatively.

6. Outcome Measures

Primary Outcome
- Stone-Free Rate (SFR) at 3 months: defined as no residual stones or residual fragments <2 mm on non-contrast CT.

Secondary Outcomes
- Incidence of postoperative infection (SIRS criteria)
- Change in serum procalcitonin and hemoglobin levels
- Postoperative pain score (VAS)
- Hospital length of stay
- Need for secondary procedures
- Complication rate (Clavien-Dindo classification)
- Cost and stone composition analysis

7. Follow-Up
Patients will be followed up via telephone, outpatient visit, or WeChat at 3 months post-op. CT will be used to assess residual stones.

8. Statistical Analysis
SPSS will be used for data analysis.
Continuous variables: mean +/- SD, t-test or Mann-Whitney U test as appropriate.
Categorical variables: test.
Multivariate logistic regression for outcome prediction.
Multiple imputation for missing data.
$p < 0.05$ considered statistically significant.

9. Safety and Monitoring
Case report forms (CRFs) will be completed for each subject.
Data will be reviewed by monitors and verified by data managers.
Serious infections (e.g., temp > 40, HR > 140 bpm, PCT > 100, bacteremia) may lead to trial withdrawal for safety.

10. Ethics and Regulatory Compliance
Approved by institutional ethics committees.
Personal information will be kept confidential and stored securely.
Regulatory bodies may audit data when required.
Participants may withdraw at any time without penalty.

11. Publication Plan
Results will be submitted to peer-reviewed journals (SCI-indexed or national core journals) and presented at academic conferences.