Informed Consent Form (ICF)

Document for ClinicalTrials.gov PRS Submission

Official Study Title:

Hemostatic Efficacy and Safety Analysis of Norepinephrine-Containing Irrigation Fluid During su-fURS Combined with NPUAS Lithotripsy

NCT Number: Not yet assigned

Document Date: 04 March 2025

ICF Version: V2.0

Sponsor: Geriatric Hospital of Nanjing Medical University

Ethics-Approved Version: Yes

Document Format: PDF/A-1b

Dear Study Participant:

You are being invited to participate in the research study entitled *Hemostatic Efficacy and Safety Analysis of Norepinephrine-Containing Irrigation Fluid During su-fURS (Single-Use Flexible Ureteroscope) Combined with NPUAS (Negative-Pressure Ureteral Access Sheath) Lithotripsy*, approved by. This study will be conducted at Geriatric Hospital of Nanjing Medical University. A total of 55 participants will be enrolled on a voluntary basis. The study period is from March 2025 to December 2026. This research has been reviewed and approved by the Ethics Review Committee of Geriatric Hospital of Nanjing Medical University.

Why are we conducting this study?

Flexible ureteroscopy combined with a negative-pressure ureteral access sheath is a common treatment for upper-urinary-tract stones and delivers high stone-free efficiency. However, this procedure has several drawbacks:

1. High out-of-pocket medical expenses impose a heavy financial burden on patients;
2. Use of the negative-pressure sheath may increase the risk of intraoperative bleeding;
3. Compared with reusable flexible ureteroscopes, single-use digital flexible ureteroscopes have lower image resolution. Intraoperative bleeding reduces stone-free rates and procedural safety.

This study aims to resolve poor surgical visualization caused by intraoperative bleeding, improve stone-free rates and procedural safety, and lower the re-operation rate for upper-urinary-tract stones.

What will happen if you take part in this study?

Should you agree to participate in this study, you will be randomly assigned to receive norepinephrine-containing irrigation fluid at one of four concentrations: 2 mg/3L, 4 mg/3L, 6 mg/3L or 8 mg/3L. A within-subject sequential-period control design will be adopted. Normal-saline irrigation fluid will be applied first to serve as the control phase, followed by diluted norepinephrine-containing irrigation fluid for the study intervention phase. The study intervention will be stopped immediately if significant changes in vital signs occur during the norepinephrine irrigation phase.

The pharmacological effect of the study drug lasts approximately 1-2 hours. Your vital signs will be monitored within 8 hours after surgery. Final vital-sign checks will be performed prior to hospital discharge. Given the transient effect and short half-life of norepinephrine, which is also an endogenous substance in human tissues, no further follow-up will be required provided your vital signs are stable at discharge.

Who is suitable for participation?

1. Patients aged 18-75 years, with definite surgical indications for upper-urinary-tract stones, who can tolerate general anesthesia and accept the proposed surgical procedure.

Who should NOT take part in this study?

1. Patients with non-upper-urinary-tract stones;
2. Patients' intolerant to flexible-ureteroscope surgery;
3. Poorly-controlled hypertension （blood pressure＞160/100 mmHg）;

4. Patients with coronary artery disease.

What are the potential risks of participation?

All therapeutic medications carry a risk of adverse reactions. Based on its pharmacological properties, norepinephrine may cause intraoperative blood-pressure elevation and heart-rate fluctuations. Nevertheless, the norepinephrine solution used in this study is highly diluted, and systemic absorption is minimal. Your blood pressure and heart rate will be continuously monitored intraoperatively. If clinically significant abnormalities occur, anesthesiologists will administer vasodilators for timely symptomatic management. Surgical procedures will only continue while vital signs remain stable. Post-operative vital-sign surveillance will be implemented to detect and manage potential adverse reactions. If you sustain study-related harm, relevant medical treatment and compensation will be provided in accordance with national regulations.

What are the potential benefits of participation?

Your clinical condition may improve with participation in this study. The investigational intervention may offer improved safety and a higher stone-free rate. Findings from this study may also help establish safer and more effective treatment options for other patients suffering from similar stone disease.

Will you incur any costs for participating?

The study drug norepinephrine will be provided free-of-charge to compensate for inconveniences related to study participation. Routine surgical costs will be charged as standard clinical care. You will not be required to pay any study-related fees. No travel allowance or other compensation will be provided.

Will your personal information be kept confidential?

Your medical records will be stored within the hospital. Authorized investigators, study administrative authorities and the Ethics Review Committee may access your medical records for study-related purposes. No personal identifying information will be disclosed in any public reports derived from this study. Every reasonable effort will be made to protect the privacy of your medical data within the limits permitted by law.

Can you make your own decision about participation?

Participation in this study is entirely voluntary. You may refuse enrolment or withdraw from the study at any time during the research without compromising your standard clinical care. If you decline participation or withdraw mid-study, alternative treatment options are available, including single-use flexible-ureteroscope lithotripsy without norepinephrine irrigation (with or without negative-pressure access sheath). The study intervention may offer improved safety compared with alternatives: better intraoperative visualization may enhance stone-removal efficiency, reduce risks of residual stones and stone recurrence, and lower long-term treatment-related costs. Investigators may discontinue your participation if you fail to comply with study procedures or experience study-related injury. If you decide to withdraw from the study, please inform your treating physician. You may be asked to undergo relevant examinations for the protection of your health.

Study Participant Statement

I have read the above-mentioned introduction to this study and fully understand the potential risks and benefits of taking part. I voluntarily agree to participate in this research study.

I consent □ or decline □ to allow my medical records and pathological specimens to be used for research other than the present study.

Participant Signature: _____ Date: ____ Year ____ Month ____ Day ____ Hour ____ Minute

Contact Telephone: _____

Legal Representative Signature (if applicable): _____

Date: ____ Year ____ Month ____ Day ____ Hour ____ Minute

Relationship with Participant: _____ Contact Telephone: _____

Investigator Statement

I confirm that I have explained the full details of this study to the participants, with special emphasis on the potential risks and benefits associated with study participation.

Physician Signature: Wu Chuang Date: ____ Year ____ Month ____ Day ____ Hour ____ Minute

Contact Telephone: +8618156836569

Ethics Review Committee, Geriatric Hospital of Nanjing Medical University / Jiangsu Geriatric Hospital, Contact Phone: 025-89699426