

Informed Consent Form

Video-Assisted Ablation of Pilonidal Sinus (VAAPS) Combined with Loose
Glove-Edge Seton Drainage for Postoperative Self-Care: A Prospective Single-Arm
Cohort Study (PKUPH-PS01)

Sponsor: Peking University People's Hospital

Principal Investigator: Bozhi Hu, MD, MD

NCT Number: TBD (Pending Registration)

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For submission to [ClinicalTrials.gov](https://clinicaltrials.gov)

This document contains no identifiable participant information.

Study Title

Video-Assisted Ablation of Pilonidal Sinus (VAAPS) Combined with Loose Glove-Edge Seton Drainage for Postoperative Self-Care: A Prospective Single-Arm Cohort Study (PKUPH-PS01)

Invitation to Participate

You are being invited to participate in a research study because you have been diagnosed with sacrococcygeal pilonidal sinus and are scheduled for VAAPS surgery. Please read this form carefully before deciding whether to participate.

1. What is the study about?

This study evaluates the outcomes of VAAPS combined with a loose seton technique for patients who travel from other cities and will perform wound care at home. The seton helps keep the wound open and prevents fluid buildup, potentially avoiding the need for daily flushing at the hospital.

2. Why is this study being done?

Standard VAAPS requires daily wound flushing and frequent hospital visits. Many patients cannot return to the hospital for this care. We want to learn whether the loose seton technique allows safe and effective wound healing when patients care for the wound at home.

3. What will happen if I participate?

- You will undergo standard VAAPS surgery performed by the surgical team
- Two thin rubber strips will be placed around the wound openings during surgery
- You will receive wound care instructions before discharge
- You will remove the first strip at about 1 week and the second at about 3 weeks
- You will complete follow-up assessments at 1 day, 1 week, 2 weeks, 4 weeks, 6 weeks, 3 months, 6 months, 1 year, and 3 years after surgery
- Follow-up may be in person, by phone, or via WeChat

4. What are the risks and discomforts?

The risks are those associated with standard VAAPS surgery, including: pain, bleeding, wound infection, delayed healing, hematoma, seroma, and recurrence. The seton strips may cause minor irritation or discomfort during the wearing period. There may be unknown risks. A 24-hour contact number will be provided for any concerns.

5. Are there benefits?

You may benefit from the seton technique by avoiding the need for daily hospital flushing and reducing travel and costs. The information from this study may help future patients with pilonidal sinus disease. You may not directly benefit from participating.

6. What are my alternatives?

You may choose not to participate. Your decision will not affect your medical care. Alternative treatments include conventional open surgery, flap procedures, or other minimally invasive approaches, which your surgeon will discuss with you.

7. Confidentiality

Your personal information will be kept confidential. Study data will be coded with a study number; your name and medical record number will not appear in study databases. Data are stored securely at Peking University People's Hospital. Results may be published in scientific journals, but you will not be identified.

8. Voluntary Participation

Participation is entirely voluntary. You may withdraw at any time without penalty and without affecting your medical care. If you withdraw, data collected up to that point may be retained and analyzed.

9. Contacts

Principal Investigator: Bozhi Hu, MD

Department of Gastrointestinal Surgery, Peking University People's Hospital

For questions about the study or to report a research-related injury, please contact the research team.

For questions about your rights as a research participant, contact the Ethics Committee of Peking University People's Hospital.

10. Consent

By signing below, I confirm that I have read and understood this consent form, have had the opportunity to ask questions, and agree to participate in this study.

Participant Signature: _____

Date: _____

Witness Signature: _____

Date: _____