The Value of Bowel Sounds in Evaluating Postoperative Intestinal Function Recovery in Colorectal Cancer Patients

INFORMED CONSENT FORM

Study Period: March 2026 – July 2026
Project Number: ZNH-2025-BA-02
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Invitation to Participate：

You are being invited to participate in a clinical research study. This informed consent form provides information to help you decide whether to take part in this study. Please read the following information carefully. If you have any questions, please feel free to ask the study investigators.

Your participation in this study is entirely voluntary. This study has been reviewed and approved by the Medical Ethics Committee of Zhongnan Hospital of Wuhan University.

1. Purpose of the Study

Colorectal cancer is the third most common malignancy worldwide and the second leading cause of cancer-related mortality. In recent years, both the incidence and mortality of colorectal cancer have been increasing in China. Surgical resection remains the primary curative treatment for colorectal cancer. However, postoperative gastrointestinal dysfunction, including decreased bowel motility, postoperative ileus, or even early postoperative bowel obstruction, may occur due to surgical trauma and anesthesia, leading to delayed recovery and prolonged hospitalization.

Bowel sounds are acoustic signals generated during intestinal peristalsis and can reflect gastrointestinal functional status. Traditional auscultation is subjective and lacks reproducibility, limiting its value in accurately assessing postoperative bowel function recovery.

This study aims to use a self-developed intelligent digital bowel sound detection system to objectively and continuously record postoperative bowel sounds in patients undergoing colorectal cancer surgery. By analyzing postoperative bowel sound characteristics, this study seeks to evaluate their clinical value in predicting bowel

function recovery and early postoperative bowel obstruction, thereby providing objective evidence for postoperative management.

2. Study Procedures

If you agree to participate in this study, bowel sound monitoring and related data collection will be conducted during your postoperative recovery period. The procedures are as follows:

1. **Timing of Bowel Sound Recording**
   Bowel sounds will be recorded at the following postoperative time points:
   2 h, 6 h, 24 h, 36 h, 48 h, 60 h, and 72 h after surgery.
   At each time point, bowel sounds will be recorded continuously for approximately **5 minutes**.
2. **Method of Recording**
   A non-invasive bowel sound detection device will be used. Several sensors will be attached to the surface of your abdominal skin to collect bowel sound signals. The procedure is painless, radiation-free, and does not interfere with your normal activities or rest.
3. **Collection of Clinical Information**
   Relevant clinical data will be collected concurrently, including surgical approach, postoperative recovery indicators (such as time to first flatus and bowel movement), laboratory test results, and imaging data. All collected information will be used solely for scientific research purposes.
4. **Follow-up**
   Follow-up will be conducted during your hospital stay only. The study does not involve additional examinations or changes to your standard medical treatment.

This study does not involve drug administration, placebo control, or any therapeutic intervention. Participation will not affect your routine clinical care.

3. Potential Risks and Discomforts

This is a non-invasive observational study with minimal risk. The bowel sound recording procedure involves only skin contact with adhesive sensors. In rare cases, mild skin irritation or allergic reactions may occur, which usually resolve after removal of the sensors.

All study procedures are conducted alongside routine medical care and will not interfere with your surgery or postoperative recovery.

4. Potential Benefits

- Objective monitoring of bowel sounds may assist clinicians in assessing postoperative bowel function recovery;
- Early identification of potential gastrointestinal dysfunction may support timely clinical decision-making;
- Your participation will contribute valuable data to improve postoperative recovery monitoring strategies and promote non-invasive gastrointestinal function assessment techniques.

Please note that participation in this study does not guarantee direct personal benefit.

5. Confidentiality

Your personal information will be kept strictly confidential. All study data will be stored in a coded manner without your name or any personally identifiable information. Only authorized study personnel will have access to the data.

The results of this study may be published in scientific journals or presented at academic conferences; however, no information that could identify you personally will be disclosed.

6. Voluntary Participation and Right to Withdraw

Your participation in this study is entirely voluntary. You have the right to refuse participation or withdraw from the study at any time without providing a reason. Withdrawal from the study will not affect your medical care or your relationship with your healthcare providers.

7. Costs and Compensation

There is no cost to you for participation in this study, including the use of the bowel sound detection device and data collection. Participation will not increase your hospitalization expenses.

If any adverse events related to study procedures occur, appropriate medical care will be provided by the hospital in accordance with institutional policies.

Participant Signature Page

Statement of Consent

☐ I have read and understood the information provided above. The study investigator has explained the purpose, procedures, potential risks, and benefits of this study to me. All of my

questions have been answered. Based on this understanding, I voluntarily agree to participate in this study and understand that I may withdraw at any time without penalty.

☐ Due to lack of or limited decision-making capacity, this informed consent is signed by the participant's legal guardian or authorized representative.

Participant's Name (Printed): _____

Participant's Signature: _____

Date: _____

Legal Guardian/Authorized Representative (if applicable): _____

Signature: _____

Date: _____

Contact Information: _____

Investigator's Statement

I confirm that I have fully explained the details of this study to the participant (or their legal representative), including potential risks and benefits.

Investigator's Name (Printed): _____

Investigator's Signature: _____

Date: _____

Contact Information: _____

Note: This consent form is signed after a face-to-face explanation by the study investigator. Both the participant and the investigator will retain an original signed copy.