# Single-blind, double-arm, multi-center randomized controlled clinical study on the prevention of intestinal dysfunction after robotic/laparoscopic right hemicolectomy with RISE-type ileocecal valve functional reconstruction

# informed consent

Dear participants in the study:

shalom ！

We cordially invite you to participate in the "RISE-Style Anti-Reflux Vaginal Prosthesis Functional Reconstruction for Preventing Postoperative Intestinal Dysfunction in Right Hemicolectomy Patients: A Single-Blind, Double-Arm, Multi-Center Randomized Controlled Clinical Trial". This clinical trial is led by Dr. Xiaowei Dong, Director of General Surgery. As a medical research initiative with experimental nature, this study differs from routine healthcare services. It will be conducted at five hospitals: Second Affiliated Hospital of the Army Medical University, First Affiliated Hospital of Chongqing Medical University, North Sichuan Medical College Affiliated Hospital, Guang 'an People's Hospital of Sichuan Province, and Yibin Third People's Hospital of Sichuan Province. Approximately 188 participants are expected to join, with our center planning to enroll 108 individuals. The entire study is projected to last about three years, with your participation period spanning approximately one year. This research has been reviewed and approved by the Medical Ethics Committee of the Second Affiliated Hospital of the Army Medical University.

**I. [Why do we conduct this study?]**

Background: Laparoscopic right hemicolectomy serves as the gold-standard procedure for treating right-sided colon cancer, typically requiring resection of the affected intestinal segment including the ileocecal valve. This anatomical structure

acts as a natural gatekeeper between the small and large intestines, functioning to delay chyme passage for enhanced nutrient absorption while preventing bacterial reflux into the small intestine. However, current surgical approaches that routinely remove the ileocecal valve have led to postoperative complications such as bile acid malabsorption diarrhea and small intestinal bacterial overgrowth. These conditions often result in chronic abdominal pain and vitamin absorption disorders, significantly compromising patients' quality of life.

This study improves traditional end-to-end anastomosis by reconstructing the ileocecal valve using the terminal ileum through suture. Preliminary evidence confirms that this approach restores intestinal gate function and reduces bacterial reflux risk. We have named this innovative technique the Revolute Insert Side-End ileocecal valve reconstruction (RISE), abbreviated as RISE anastomosis.

Objective: To compare the advantages of right hemicolectomy combined with reconstruction of ileocecal flap RISE anastomosis (group 1) compared with traditional non-reconstructed ileocecal flap side-to-side anastomosis (group 2) in terms of surgical safety, tumor efficacy and postoperative intestinal function recovery.

II. [Who is suitable to participate in this study?]

Patients who meet the diagnostic criteria for right-sided colon cancer in the NCCN Colon Cancer Guidelines and can be resected by radical surgery.

**Inclusion criteria:**

①Participants aged 18-80 years; ②ASA score ≤3; ③First-time diagnosis of tumors located in the appendix, ileocecal region, ascending colon, hepatic flexure, or right one-third of transverse colon; or candidates for laparoscopic radical resection of the right half of the colon; ④No history of other gastrointestinal diseases (excluding intestinal polyps and gallstones); ⑤Willingness to participate in the study and signing an informed consent form; ⑥Complete clinical data.

**Exclusion criteria:**

① Patients with concurrent malignant tumors in other organs; ② Tumors invading adjacent local organs; ③ Patients with concurrent infections or autoimmune

diseases (such as Crohn's disease); ④ Patients with congenital or acquired metabolic disorders; ⑤ Those who had taken antibiotics or other antimicrobial agents within one month before study enrollment; ⑥ Changes in surgical plans where the resection did not include the ileocecal valve;

**Exit criteria:**

① The patient explicitly refuses to continue participating in the study or opts for reconstructive ileocecal valve anastomosis. ② Researchers determine that the patient does not meet the surgical criteria. ③ The patient is unable to complete follow-up (e.g., lost contact, refusal to undergo further examinations). ④ Participants fail to receive interventions or follow up as required by the study protocol, affecting data validity.

**Early termination criteria:**

①If the principal investigator terminates the clinical trial citing medical, ethical considerations, or the best interests of the subjects; ②If interim analysis indicates that the intervention (RISE anastomosis) fails to meet predefined efficacy targets, and continuation of the study holds no clinical significance; ③If the study demonstrates that this surgical anastomosis method will result in unacceptable postoperative complications.

**III. [Contents and Procedures of the Study]**

(1) Before you are selected for the clinical study, your doctor will ask and record your medical history. If you agree to participate in this study, please sign this informed consent form. If you do not want to participate in this study, we will also treat you according to your wishes.

(2) If you participate in this study voluntarily, the process will include the following stages:

After signing the informed consent form, you will undergo screening examinations including: ① CT plain scan and contrast-enhanced imaging of the upper abdomen, lower abdomen, and pelvis (to assess tumor size and potential metastasis);

② Blood tests (complete blood count, biochemical panel including liver function, kidney function, electrolytes, blood glucose, and lipid levels); ③ Completion of two quality-of-life questionnaires (EORTC QLQ-C30 and QLQ-CR29 scales).

This study employs a randomized controlled design. Participants are randomly assigned (like flipping a coin) with 50% chance to be placed in either group, ensuring neither participants nor physicians can influence the assignment. All groups will undergo tumor resection according to current guidelines, differing only in the method of intestinal reconnection.

Research team: After removing the tumor, doctors use an improved end-to-end anastomosis method to reconnect the bowel. This uses sutures to reconstruct a "gallbladder" structure at the end of your ileum (the gallbladder is a natural valve in the gut that controls the speed of food flow).

Control group: After tumor resection, the doctor will use the current conventional method of using a linear cutting clamps for ileocolonic side-to-side anastomosis to reconnect the intestinal tract. This method does not deliberately reconstruct the "gallbladder" structure.

After treatment, you need to come to the hospital for regular follow-up.

**Follow-up 1: 1 month after surgery**

The re-examination items include: ①Barium meal radiography of the digestive tract; ②Colonoscopy; ③Blood tests: complete blood count, biochemical panel, vitamin B12 level check, tumor marker detection (CEA, CA19-9); ④Imaging studies: full abdominal contrast-enhanced CT scan + plain scan; ⑤Body composition analysis (nutritional assessment); ⑥Completion of quality of life questionnaires (EORTC QLQ-C30 and QLQ-CR29 scales); ⑦Collection of blood and stool samples.

**Follow-up 2: 3 months, 6 months and 1 year after surgery**

The re-examination items include: ① Blood tests: complete blood count, biochemical blood, vitamin B12, tumor markers (CEA, CA19-9); ② Imaging examinations: full abdominal contrast CT + plain scan; ③ Body composition analysis (nutritional assessment) ④ Collection of blood and stool samples.

(3) After the completion of the study, the remaining samples will be destroyed. Except for this study, your information will not be used again in the future.

**IV. [Voluntary Principle of Participation]**

Before signing this informed consent form, please take a moment to carefully review the document and make an informed decision about participating in this study. If you have any questions, feel free to ask your study physician or research staff for clarification until you fully understand everything. Before committing to participate, we encourage you to discuss your decision with family and friends to ensure it is well-considered.

You have the right to refuse to participate in this study and to withdraw from the study at any time. You will not be punished or have your other legitimate rights and interests harmed for doing so.

**V. [Rights and Related Considerations of Research Participants]**

By signing this INFORMED consent form, you agree to comply with the arrangements made by the investigator based on the specific requirements of the study protocol. This study is a randomized controlled trial and you and your physician will not be able to choose/decide for you the treatment you will receive.

You need to provide truthful information about your medical history and current physical condition; inform your physician or investigator of any discomfort you experience during the study; and inform your physician or investigator of any other studies you have recently participated in or are currently participating in.

If new significant safety information related to the study or other information affecting the feasibility of the protocol is available during the study, the informed consent form will be updated in accordance with regulations. In such cases, if you still agree to continue participating in the study, you will need to sign a new version of the informed consent form.

**How to get more information?**

During the study, if there is a change in the study content or new adverse

reactions that may affect your continued participation in the study, your doctor or researcher will inform you or your guardian in time.

If you need to know more about the research, please contact researcher Wang Zihan at 13618347369.

If you have any questions about your rights and interests in this study, or if you want to report your difficulties, dissatisfaction and worries in the process of participating in this study, please contact the Medical Ethics Committee of The Second Affiliated Hospital of The Army Medical University at 023-68755422.

**VII. [Expected Risks and Discomforts related to the Study]**

No matter which group you enter, the possible risks, adverse reactions and surgical complications are not completely prevented by current medical level. We will give detailed information in the form of informed consent before surgery.

There is a risk of complications with RISE anastomosis (intervention group):

1. Risk of anastomotic stenosis: Anastomotic stenosis during the healing process is one of the routine surgical risks. In this study, RISE anastomosis was performed at the end of the folded ileum, which may increase the risk of anastomotic stenosis.

We will take the following measures to prevent this risk: (1) During the operation, we will re-evaluate the ileum status, and patients with poor ileal status will be withdrawn from the study and treated routinely. (2) The follow-up plan of this study includes the evaluation of the anastomosis, which can detect the tendency of stricture early.

If the anastomosis is narrowed, we will take the following treatment measures: (1) balloon dilation under colonoscopy; (2) stent placement under colonoscopy; (3) surgical resection of the narrowed part of the intestinal tract and reanastomosis if necessary.

If you experience any discomfort, new changes in your condition, or any unexpected situation during the study, whether or not it is related to the study, you should inform your doctor immediately. The doctor will make a judgment and give appropriate medical treatment.

During your study, you need to go to the hospital for follow-up and some

examinations on time, which will take up some of your time and may cause you trouble or inconvenience.

**VIII. [Measures for dealing with research-related damage when participating in the study]**

The researchers will purchase insurance for this study. During the study, if any adverse event occurs in the clinical trial, it will be determined whether it is related to the study, and the researchers will provide corresponding compensation for the damage related to the study in accordance with relevant laws and regulations in China.

**IX. [What benefits can I get by participating in this study?]**

1. This study may accelerate the recovery of your intestinal function and reduce the risk of postoperative diarrhea and malnutrition, but we can not guarantee that it will definitely work for you.

2. The relevant data and information obtained in this study will provide a more reliable evidence-based medical basis for the future radical surgery of right colon, benefiting patients with right colon cancer in the future.

**X. [What are my treatment options if I don't participate in the study?]**

If you do not participate in this study, you can receive your doctor's routine treatment: 1. Right hemicolectomy + ileocolic side-to-side anastomosis; 2. Systemic chemotherapy; 3. Targeted therapy; 4. Immunotherapy.

**XI. [Research Costs and Related Compensation]**

Regardless of your assigned group, all participants will undergo standard medical examinations during the screening phase. The perioperative procedures will follow clinically established protocols, with required follow-up visits also being routine medical care. Preoperative examination fees, surgical charges, and hospitalization costs will be borne by participants. By enrolling in this study, you'll receive full coverage for gastrointestinal barium meal radiography examinations at our department. Upon completing all scheduled follow-up visits as outlined in the protocol, you'll receive a total subsidy of 800 yuan.

**XII. [Protection of Personal Information and Privacy]**

We assure you that your medical records and information will be used exclusively for this clinical study and will not be shared with third parties. The data generated from this research will not be included in your medical documentation. While the findings may be published in academic journals at a future date, your personal information will never be referenced in such publications.

Under the condition that the confidentiality principle and relevant regulations are not violated, researchers, research authorities, ethics committees and supervision and management department personnel may access your original medical records and related information.

# Informed consent form · Consent signature page

**[Consent Statement]**

The researcher has explained the aforementioned information to me item by item. I have taken sufficient time to read and understand all contents of this informed consent form. All questions regarding the study have been answered satisfactorily. I am fully aware of the potential risks and benefits associated with participating in this research. I voluntarily sign this informed consent form and participate in this study. The informed consent process was conducted without coercion or inducement. I will receive a signed and dated copy of this informed consent form.

Research participant signature: Signature date: Year Month Day

Research participant signature: Signature date: Year Month Day

Contact number of study participants:

Guardian's signature: Date of signature: Year, Month and Day

Guardian's signature: Date of signature: Year Month Day

Relationship between guardian and research participant:

Guardian's contact number:

(If the research participant is not a person with civil capacity or limited civil capacity, the guardian's signature and date of signature are required)

Signature of impartial witness: Date of signature: Year, month and day

Signature of impartial witness: Date of signature: Year, month and day

Contact number of impartial witness:

**[Researcher Statement]**

I hereby confirm that I have explained the details of this study to the participants, including the potential risks and benefits involved in participation. All questions from the participants have been answered, and they participated voluntarily. This informed consent form is made in duplicate, with one copy retained by the researcher and one by the participant after signing.

Researcher's signature: Signature date: Year Month Day

Researcher's signature: Signature date: Year Month Day

Contact number of researchers: