Official Title:

THE ROLE OF MECHANICAL BOWEL PREPARATION IN LAPAROSCOPIC RIGHT HEMICOLECTOMY WITH TOTALLY INTRACORPOREAL ANASTOMOSIS FOR COLON CANCER:

A RANDOMIZED CONTROLLED TRIAL

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INFORMATION SHEET AND INFORMED CONSENT FORM

Study Title:
The Role of Mechanical Bowel Preparation in Laparoscopic Right Hemicolectomy with Totally Intracorporeal Anastomosis: A Randomized Controlled Trial
Sponsor: Self-funded
Principal Investigator:
Tran Duc Huy, MD, MSc
Institution:
University of Medicine and Pharmacy at Ho Chi Minh City – University Medical Center Ho Chi Minh City

I. Study Purpose and Procedures

1. Purpose

Mechanical bowel preparation (MBP) prior to colorectal surgery is commonly used to reduce bowel contents, thereby potentially decreasing the risk of surgical site infection and anastomotic complications.

However, MBP may cause discomfort, nausea, vomiting, poor tolerance, and impaired oral intake before surgery, which may increase the risk of fluid and electrolyte imbalance postoperatively. Therefore, in some procedures, particularly right hemicolectomy, MBP is not always considered necessary.

With the increasing adoption of totally intracorporeal anastomosis in laparoscopic colectomy, unprepared bowel and residual fecal content may increase the risk of intraoperative contamination during anastomosis construction. Thus, MBP may be beneficial in this setting.

This study aims to determine whether mechanical bowel preparation reduces postoperative complications without negatively affecting recovery in patients undergoing laparoscopic right hemicolectomy with totally intracorporeal anastomosis.

2. Study Procedures

Eligible patients with right-sided colon cancer indicated for laparoscopic right hemicolectomy with totally intracorporeal anastomosis will be enrolled.

Study period: From September 2025 to September 2027

II. Risks and Benefits

Risks and Disadvantages

Patients receiving mechanical bowel preparation may experience:

- Dehydration
- Electrolyte imbalance
- Discomfort

Benefits

- Undergoing laparoscopic right hemicolectomy with intracorporeal anastomosis, which may:
    - Reduce postoperative pain
    - Enhance recovery
    - Improve cosmetic outcomes

Costs

- Patients will undergo standard diagnostic and preoperative procedures; therefore, **no additional costs** will be incurred.
- Follow-up visits are part of routine cancer care. Participation in this study does not increase the number of visits or associated costs.

III. Prevention and Management of Adverse Events

- Strict inclusion and exclusion criteria are applied to avoid enrolling high-risk patients (e.g., swallowing disorders, heart failure, renal failure, patients >80 years old).
- Patients undergoing MBP will be carefully instructed and monitored according to standard bowel preparation protocols.
- All patients will be hospitalized and closely monitored.
- If patients develop vomiting, dehydration, or electrolyte imbalance:
    - Laboratory tests will be performed
    - Laxatives will be discontinued
    - Fluid replacement will be administered as appropriate

IV. Contact Information

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V. Voluntary Participation

Participation in this study is entirely voluntary.
Participants:

- Are not obligated to participate
- May withdraw at any time
- Will not have their treatment or care affected by withdrawal

VI. Confidentiality

- Personal identifying information will be kept strictly confidential throughout the study and after publication.
- Published data will include only study codes and hospital record numbers.
- Medical information will also be kept confidential.

- Only authorized study investigators will have access to collected data. No third party will be allowed access.

VII. CONSENT TO PARTICIPATE

I have read and understood the information provided above. I have had the opportunity to ask questions and have received satisfactory answers. I have discussed the study with the investigator.

I have received a copy of this information sheet and voluntarily agree to participate in this study.

Participant's Name: _____

Signature: _____

Date: _____

Investigator's Statement:

I confirm that the participant has read (or has had read to them) the information above. The study has been explained fully, and the participant has understood the nature, risks, and benefits of participation.

Investigator's Name: _____

Signature: _____

Date: _____