Informed Consent Form

Title： Drainage Fluid Biomarkers and Postoperative Gastrointestinal Dysfunction in Colorectal Surgery. A Monocentric Prospective Observational Study

NCT number: NA yet

Study data: 2024.1.08

Informed Consent Form

Dear Sir/Madam_____:

We are conducting a study titled "*Drainage Fluid Biomarkers and Postoperative Gastrointestinal Dysfunction in Colorectal Surgery. A Monocentric Prospective Observational Study*" You are eligible to participate in the study, and we would like to invite you to take part. This informed consent form will explain the purpose, procedure, benefits, risks, and possible inconvenience or discomfort to you. Please read it carefully and decide whether or not you want to participate in the study. If you have any questions, please do not hesitate to ask, and your doctor will be happy to answer them. If you wish, you can also discuss your decision with your family and friends.

1.What was the purpose of conducting this study?

Postoperative gastrointestinal dysfunction (POGD), often referred to as postoperative ileus (POI) after colorectal surgery, is characterized by symptoms such as nausea, vomiting, abdominal distension, and delayed bowel movements. The incidence of this issue varies among medical institutions, impacting patient nutrition, prolonging hospital stays, and increasing healthcare costs.

The complex pathogenesis of POGD involves a brief neurogenic phase (within 3 hours) and a more prolonged inflammatory phase (beginning at 3-4 hours and lasting for days). The inflammatory phase is crucial and is recognized as initiated by mast cells and damage-associated molecular patterns that activate macrophages in the intestinal muscle layer. Subsequently, it triggers a series of cascading inflammation reactions through the release of inflammatory factors and recruitment of inflammatory cells, which contributes to the development and exacerbation of POGD. Studies have demonstrated changes in inflammatory cells and factors in the abdominal fluid following abdominal surgery, emphasizing the clinical significance of analyzing drainage fluid to predict postoperative gastrointestinal function.

This study analyzes inflammatory markers in drainage fluid following laparoscopic colorectal cancer surgery. The aim is to enhance the accuracy of predicting

gastrointestinal recovery outcomes and contribute to the evolving field of Enhanced Recovery After Surgery (ERAS).

2.Who will be invited to participate in the study?

Inclusion Criteria:

Preoperative diagnosis of colorectal cancer through colonoscopy biopsy.

Patients aged 18-80 years.

Underwent laparoscopic radical resection for colorectal cancer with confirmed postoperative pathology.

No prior radiotherapy, chemotherapy, or immunotherapy before surgery.

Voluntary participation in the study and signing of a written informed consent form.

3.How many people will participate in the study?

This study is planned to recruit **63** subjects.

4. How was the study conducted?

Type: This is a prospective single-center observational study.

Intervention:

Drainage fluid was collected from patients on the first and third postoperative days to test the levels of four biochemical tests (total protein, albumin, lactate dehydrogenase [LDH], adenosine deaminase [ADA]).

Cytological examination of abdominal drainage fluid on the first postoperative day and the third postoperative day, calculation of neutrophil-lymphocyte ratio (NLR), lymphocyte-monocyte ratio (LMR), prognostic nutritional index (PNI).

Peripheral blood cytology tests on the first postoperative day and the third postoperative day, calculation of Neutrophil-lymphocyte ratio (NLR), lymphocyte-monocyte ratio (LMR), platelet lymphocyte ratio (PLR), systemic immunoinflammatory index (SII)

Primary Objective: This study aims to investigate the inflammatory markers LDH, ADA, albumin, NLR, PNI, and LMR in the peritoneal drainage fluid on the first and third days following colorectal cancer surgery, and their correlations with postoperative gastrointestinal dysfunction (POGD).

Expected duration of study: from February 18, 2024 to October 1, 2024

5. What are the risks and adverse reactions faced by the subjects participating in this study, and how should they be managed appropriately?

By participating in this study, you will not experience any study-related adverse effects.

6. Is participation in and completion of the study mandatory?

Your participation in this study is entirely voluntary. If you choose not to participate, you can decline without any negative impact on your current or future healthcare. Even after agreeing to participate, you have the right to change your mind at any time and inform the researcher that you wish to withdraw from the study. Doing so will not affect your access to regular health care. When you decide to discontinue participation in this study, please promptly inform your study doctor. The study doctor will be able to offer advice and guidance regarding your health condition.

In principle, after you have withdrawn from the study, the researcher will keep your information strictly confidential until it is eventually destroyed and will not use or disclose it any further during this period. However, there are very limited circumstances in which the researcher may continue to use or disclose your information, and we will request your consent again. These circumstances include:

- Omit any personal information that may affect the scientific validity of the study results

or the assessment of data security.

- Provide limited information for research, teaching or other activities. This information does not include your name, ID number, or any other personal information that identifies you.

When schools and government regulators need to monitor research, they will ask to see all research data, including details of your participation in the research at the time.

7. Were subjects paid for their participation in the study?

You may not receive direct payment for participating in this study, but you can have your drainage fluid tested at no cost!

Researcher's statement

I have informed the subject about the background, purpose, steps, risks and benefits of the study " *Drainage Fluid Biomarkers and Postoperative Gastrointestinal Dysfunction in Colorectal Surgery. A Monocentric Prospective Observational Study* ", and I have given him/her enough time to read the informed consent form, to discuss the study with others, and to answer his/her questions about the study. I have informed the subject that he/she can contact ____at any time if he/she has any problems related to the study, and the **Medical Ethics Committee of**_____ at any time if he/she has any problems related to his/her own rights/interests, and provided him/her with accurate contact information; I have informed the subject that he/she can withdraw from the study; I have informed this subject that he/she will be provided with a copy of this informed consent form containing my signature and his/her signature."

_____ _____

Signature of researcher

who obtained informed consent date

Subject's statement

I was informed about the background, objectives, steps, risks and benefits of the study " *Drainage Fluid Biomarkers and Postoperative Gastrointestinal Dysfunction in Colorectal Surgery. A Monocentric Prospective Observational Study* ". I was given plenty of time and opportunity to ask questions and was satisfied with the answers. I was also told who to contact if I had any questions, difficulties, concerns, suggestions for the study, or if I needed more information or help with the study. I have read this consent form and agree to take part in this study. I understand that I can withdraw from this study at any time during the study for any reason. I have been told that I will receive a copy of this consent form with my signature and the researcher's signature on it."

_____ _____

Subject's signature data

_____ _____

Signature of the

legal representative data

Relationship with the subject _____