Informed Consent Form • Informed Disclosure Page

(Version:V1.0 Version Date:2025.3.28)

Dear Subject:

We would like to invite you to participate in a(Clinical Experimental Study on the Impact of PEG Laxative for Bowel Preparation on Intestinal Microorganisms in Patients with Cholecystectomy)study, Principal Investigator of this study: ProfessorXXX, Tongji Hospital Affiliated to Tongji Medical College, Huazhong University of Science and Technology.The study protocol has been reviewed and approved by the Medical Ethics Committee of Tongji Hospital Affiliated to Tongji Medical College, Huazhong University of Science and Technology for clinical research.

Before deciding whether to participate in this study, please read the following content as carefully as possible. It can help you understand the study, why it is being conducted, the procedures and duration of the study, as well as the potential benefits, risks and discomforts that may result from participating. If you wish, you may also discuss it with your relatives and friends, or ask your doctor for explanations to help you make a decision.

If you are currently participating in other clinical studies, please be sure to inform your research doctor or researchers. Thank you for your support of this study.

1.Why is this study being conducted?

Colonoscopy is a necessary item for colorectal cancer physical examination. For high-risk groups, annual physical examination is the most effective method for early prevention; currently, in colonoscopy, a large amount of polyethylene glycol (PEG2000-4000) is used as a laxative and lubricant; the extensive use of PEG can cause long-term and irreversible damage to intestinal microorganisms, posing great harm to health(Tropini, Lin Moss et al. 2018).

The gallbladder is a sac-like organ located below the liver, whose main

functions include storing and concentrating bile, regulating biliary pressure, participating in the digestion and absorption of fats, and protecting the intestinal mucosa. Due to the prevalence of gallbladder diseases such as gallbladder stones and cholecystitis, cholecystectomy is a common surgery worldwide. Laparoscopic cholecystectomy (LC) has become the preferred surgical method for benign gallbladder diseases due to its advantages of minimal trauma and rapid recovery. However, cholecystectomy may affect the patient's digestive function. After surgery, bile acids are continuously excreted into the duodenum, which may lead to symptoms such as indigestion and steatorrhea, and may even promote the development of colorectal cancer. In addition, cholecystectomy may affect the composition of intestinal microorganisms, thereby affecting the health of the host.

This study will observe the impact of PEG laxatives on intestinal microorganisms. By analyzing the changes in intestinal microecology before and after colonoscopy, we aim to design better bowel cleansing drugs and intestinal repair probiotics to further reduce the adverse effects of colonoscopy on patients. At the same time, we will explore the interaction and significance of the gallbladder with intestinal microorganisms.

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

Patients who have undergone cholecystectomy within the pasttenyears.

3.Participating institutions and estimated number of participants

The participating institutions include Tongji Hospital Affiliated to Tongji Medical College, Huazhong University of Science and Technology, and the School of Life Science and Technology, Huazhong University of Science and Technology. Approximately20 participants will be included in this study.

4.What will be required if you participate in the study?

1. Before you are enrolled in the study,the doctor will inquire about and record your medical history, and conductroutine inquiries about colonoscopy preparation and whether you have had

a cholecystectomy.

If you are eligible, you mayvoluntarily participate in the study and sign the informed consent form.

If you are unwilling to participate in the study, we will provide treatment according to your wishes.

2. If you voluntarily participate in the study, the following steps will be taken:

1. On the day you sign the informed consent form,you will receive6fecal sample collection kits

2. On the day you receive the materials, fill out a questionnaire and submit it to the outpatient doctor.

3. At thedesignated sampling time,collect a fecal sample, and try to select the middle part of the stool that is not contaminated by urine. After collecting the fecal sample, please contact researcherXXX, phone number XXX, mailing address: XXX. Choose freight collect for shipping.

4.During the study, we need to collect some of your specimens, and we will collect10g of feces each time, totaling5times (stool before colonoscopy, first non-watery stool after colonoscopy, stool 1 month after colonoscopy, stool 3 months after colonoscopy,stool 6 months after colonoscopy).Your samples will only be used forexperimentalresearch.

3. Other matters requiring your cooperation:

Collect fecal specimens at the designated time, and do not take antibiotics, probiotics, prebiotics and other products during the study period.

5. Potential Benefits of Participating in the Study

Testing your specimens will help analyze your intestinal microecology and the changes in intestinal microecology before and after colonoscopy, providing a basis for the design of better bowel cleansing drugs and the development of intestinal repair probiotics for the benefit of society. At the same time, it will explore the interaction and significance of the gallbladder with intestinal microorganisms.

6. Potential Adverse Reactions, Risks, Discomforts, and Inconveniences of Participating in the Study

Potential discomforts in this study include: psychological and sensory discomfort caused by fecal sampling at home by the subject, including nausea and vomiting.

7. Related Costs

Fecal sampling kits used in this experiment are provided free of charge. Mailing costs for fecal samples are borne by this project, and high-throughput testing of fecal samples is also borne by this project. If discomfort occurs during the trial due to other reasons, the related medical expenses will not be borne by this project.

8. Confidentiality of Personal Information

Your medical records (research medical records/CRF, laboratory test sheets, etc.) will be kept intact at the hospital where you are treated. Doctors will record the results of laboratory tests and other examinations in your medical records. Researchers, ethics committees, and regulatory authorities will be allowed to access your medical records. Any public reports on the results of this study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical information to the extent permitted by law.

In accordance with medical research ethics, except for personal privacy information, trial data will be available for public inquiry and sharing, which will be limited to web-based electronic databases to ensure that no personal privacy information is disclosed.

9. How to Obtain More Information?

You may ask any questions about this study at any time and receive corresponding answers.

If there is any important new information during the study that may affect your willingness to continue participating, your doctor will notify you in a timely manner.

10. Voluntary Participation and Withdrawal from the Study

Participation in the study is entirely voluntary. You may refuse to participate in this study or withdraw from it at any time during the study, which will not affect your relationship with the doctor, your medical treatment, or cause any loss of other benefits.

For your best interests, the doctor or researcher may discontinue your participation in this study at any time during the process.

If you withdraw from the study midway, for your health benefit, you may be asked about your use of the study drug, and if the doctor deems it necessary, you may also be required to undergo physical examinations and laboratory tests, which will be beneficial to your health.

If you need to take any other treatment due to changes in your condition, you can take other treatments at any time, and please truthfully inform the doctor afterwards.

11. What to Do Now?

Whether to participate in this study is decided by you (and your family). Before making a decision to participate, please ask your doctor as many questions as possible.

Thank you for reading the above materials. If you decide to participate in this study, please inform your doctor, who will arrange all matters related to the study for you. Please keep this information.

Informed Consent Form. Consent Signature Page

Project Name:_____

Undertaking Institution:_____ Tongji Hospital Affiliated to Tongji Medical College, Huazhong University of Science and Technology

Consent Statement

I have read the above introduction about this study and have had the opportunity to discuss and ask questions about the study with the doctor. All the questions I raised have been satisfactorily answered.

I am aware of the potential risks and benefits of participating in this study. I understand that participation is voluntary, I confirm that I have had sufficient time to consider this, and I understand that:

- I can consult the doctor for more information at any time.
- I can withdraw from this study at any time without discrimination or retaliation, and my medical treatment and rights will not be affected.

I agree to allow the ethics committee or regulatory authorities to access my research data.

I will receive a signed and dated copy of the informed consent form.

Finally, I decide to agree to participate in this study and promise to comply with the doctor's advice as much as possible.

Subject's Signature:_____ _____Year_____Month_____Day

Contact Phone Number:_____

I confirm that I have explained the details of this trial to the patient, including their rights, potential benefits and risks, and have provided them with a signed copy of the informed consent form.

Researcher's Signature:_____ _____Year_____Month_____Day

Contact Phone Number:_____