Effects of early enteral nutrition on pancreatic fistula and long-term prognosis after distal pancreatectomy or enucleation of pancreatic tumors

INFORMED CONSENT DOCUMENT（V2.0　2021-9-9）

Please understand the possible risks and benefits of the research before you make an informed decision to participate in the study. This process is called informed consent. The Ethics Committee (EC) has approved the information in this consent form and approved the research physician to conduct this research. An Ethics committee (EC) is an independent group of experts and nonspecialists designed to help protect the rights of research subjects. It does not mean that the EC has approved your participation in the research or that the study is risk-free. This consent form may contain words that you do not understand. Ask the research physician or researcher to explain anything you do not clearly understand. You may take home an unsigned copy of this consent form to think about or consult with family, friends, or anyone you choose before making a decision. If you decide to participate in this research, you will be asked to read and sign this consent form to confirm that you have understood the study instructions and agreed to participate. You will receive a copy of the signed consent form. As you read this consent form, please note: "you" and "your" in the text refer to the person participating in the research and not to the parent/guardian or legally authorized representative who may have signed this consent form on behalf of the research participant.

Dear Sir/Madam:

We invite you to participate in clinical research entitled “Effects of early enteral nutrition on pancreatic fistula and long-term prognosis after distal pancreatectomy or enucleation of pancreatic tumors”. Before deciding to participate in this research, please read the following as carefully as possible to understand the research objectives, procedures, durations, and the benefits, risks, and discomfort associated with participating in the research. You can also discuss it with your kinsfolk or friends to help you decide whether to participate in the study. If you have any questions, please address them to the doctor or investigator responsible for the research. You are free to decide whether to take part in this research trial. If you choose not to participate, this will not affect the care you get from your doctors.

This informed consent form contains three parts. The first part is the introduction of this research and some problems that may encounter in the study, and the second part is the consent statement of the subjects. Please sign your name in the corresponding position in the second part after reading the first part carefully. The doctor or researcher will declare and sign in the last section.

PART1

1. Background of this subject

Postoperative pancreatic fistula (POPF) is one of the most common complications after pancreatic surgery. In 2016, the International Study Group of Pancreatic Surgery (ISGPS) revised the original classification definition of pancreatic fistula, renamed grade A pancreatic fistula as biochemical fistula, and no longer included in the pancreatic fistula. The definition of grade C pancreatic fistula is more strict. The postoperative pancreatic fistula increases the risk of other postoperative complications, such as bleeding, multiple organ failure, and even deaths.

Distal pancreatectomy and enucleation are the standard treatment for pancreatic body and tail tumors. The reported incidence of clinically relevant pancreatic fistula remains at 6%-34% due to the anatomical characteristics of the pancreas and the physiological characteristics of the patients. Despite the low mortality caused by pancreatic fistula, there's still a considerable percentage of patients suffering from readmission and percutaneous drainage.

In recent years, with the continuous deepening of the enhanced recovery after surgery (ERAS), an increasing number of studies have reported that ERAS does not increase the incidence of postoperative pancreatic fistula and other complications but can significantly shorten the length of postoperative hospital stay and accelerate the recovery of patients. However, most previous studies focused on pancreaticoduodenectomy and only a small number of researches on distal pancreatectomy.

Therefore, evidence regarding whether early oral intake can be tolerated in patients undergoing distal pancreatectomy or enucleation remains to be further explored in large randomized controlled trials.

2. The main contents of this subject

A total of 106 patients who underwent laparoscopic or open distal pancreatectomy or enucleation of pancreatic tumors at the Department of General Surgery of Peking University Third Hospital from December 2021 to June 2023 were enrolled in this study.

All patients were evaluated by detailed medical history collection, physical examination, imaging examination, and/or pathological biopsy. Researchers use a random number generator to generate a randomization scheme. According to the predetermined randomization scheme, eligible patients are randomized at 1:1 to either the early feeding group or the late feeding group. The patients in the early feeding group began enteral nutrition on the third day after surgery, and the patients in the late feeding group began enteral nutrition on the 7th day after surgery. According to the differences in postoperative conditions and long-term survival effects, the relevant data on perioperative characteristics and long-term survival were obtained. The subsequent radiotherapy, chemotherapy, and other comprehensive treatment for pancreatic cancer were provided according to the postoperative pathology and condition changes. This study was approved by the Ethics Committee of Peking University Third Hospital. The Ethics committee of Peking University Third Hospital has considered that the study complies with the principles of the Declaration of Helsinki and complies with medical ethics.

3. Process and deadline of this subject

This study requires your cooperation to complete the relevant examinations and treatment. Patients were followed up after hospital discharge by telephone, letter, or e-mail regarding long-term complications, survival, and quality of life.

4. Exclusion criteria (You will be considered unfit to participate in the study if one of the following occurs)

4.1. Patients cannot tolerate surgery, such as those with a history of cardiac infarction in the past six months, cerebral infarction, severe liver, kidney, or cardiopulmonary insufficiency;

4.2. Poor compliance of patients and their authorized surrogates;

4.3. Patients with combined gastrointestinal resection;

4.4. Enrolled in another trial.

5. Possible risks, discomfort, and inconvenience of participating in the study

The two enteral nutrition methods in this program are the current clinical practice, so participating in the program itself will not increase your treatment risk. This study does not involve the collection and use of blood, tissue, and other biological samples.

During the study period, you need to go to the hospital on time for follow-up and do some necessary

examinations, which will take up some time and may cause trouble or inconvenience.

After clinical treatment, including during the study period, if you suffered from any discomfort, new changes in your condition, or any unexpected situation, whether related to the study, you should promptly notify your doctor, who will make a judgment and give appropriate medical treatment.

6. The benefit of participating in the study

If you participate in the study, the findings will have important implications for clinical decision-making in all patients with this condition.

The benefit of participating in the study include specialized follow-up, reexamination clinic, and consultation. This project will set up a follow-up, reexamination, and consultation clinic so that you can get timely and comprehensive postoperative condition consultation and monitoring.

7. The costs of participating in the study

In this study, there are no tests outside your current routine diagnosis and treatment, which will not increase your treatment costs. At present, the examination items, surgery, and postoperative follow-up of this study are routine medical procedures, and do not require additional examinations or costs.

8. Treatment of study-related injuries

If you are injured as a result of participating in the study, Peking University Third Hospital will provide the necessary medical care immediately, and bear the cost of the treatment and the corresponding financial compensation by the relevant laws and regulations. Please contact Professor Xiu at ******.

If you experience any discomfort or any unexpected situation, whether related to new medical technology research, you should notify your doctor in time, he/she will make a judgment and provide medical treatment. Doctors will do their best to prevent and treat possible harm.

If an adverse event occurs during a clinical trial, the committee of medical experts will determine whether it is related to the clinical study. The hospital will provide treatment costs and corresponding financial compensation for study-related injuries.

9. Confidentiality of Personal Information

Your medical records (medical records, physical and chemical examination reports, etc.) will be kept completely in the hospital. Doctors (researchers), professional academic committees, ethics committees, and health supervision and management departments will be allowed to access your medical records. Your

identity will not be disclosed in any public report of the results of this study. We will make every effort to protect the privacy of your medical data within the scope of the law.

10. About refusal to participate or withdrawal

You may choose not to participate in this study, or withdraw at any time after informing the investigators without discrimination or retaliation. You will begin to take food 7 days after surgery, and your medical treatment and rights will not be affected.

If you do not comply with the study protocol, or have any other reason, you may be asked to withdraw from the study without your consent.

Your participation in this study is voluntary. If you have questions related to the study, research-related injury, or rights of participants, you can contact Professor Xiu at ******.

If you have any questions related to your rights and interests, or if you would like to express your dissatisfaction and concerns about participating in this study, please contact the Office of Research Ethics, Peking University Third Hospital, at ******.

PART2

The patient (subject) consented to the statement.

I have read the above description of the study and had the opportunity to discuss it with physicians and ask questions. All my questions were satisfactorily answered.

I am aware of the risks and benefits that may arise from participation in this study. I have known that participation in the study was voluntary. I confirm that I have had ample time to consider this and understand that:

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

I also know that if I withdrew from the study, especially for treatment reasons, it would be in my best interests and the best interests of the study if I informed my doctor of the changes in my condition and

completed the corresponding physical and physical examinations.

If I need to take any other medication as a result of a change in my condition, I will seek advice from my doctor beforehand or tell my doctor so afterward.

I consent to the health management supervision department, ethics committee, or professional academic committee to access my research data.

I will be provided with a signed and dated copy of the informed consent form.

Finally, I decided to participate in the study and follow my doctor's advice as much as possible. Participant:

Name_____ Date_____ Signature _____ Tel.: _____

The legal representative of the participant:

Name_____ Date_____ Signature _____ Tel.: _____

PART3

I have informed the subject of the background, purpose, procedures, risks, and benefits of " Effects of early enteral nutrition on pancreatic fistula and long-term prognosis after distal pancreatectomy or enucleation of pancreatic tumors ". I have given him/her enough time to read the informed consent, discuss it with others, and answer his/her questions about the study. I have told the subject to contact Professor Xiu at any time when he or she has problems related to the research, and to contact the General Office of Research Ethics of Peking University Third Hospital at any time when he or she has problems related to his or her rights and interests, and provided accurate contact information. I have informed the subject that he may withdraw from the study at any time without any reason; I have informed that the subject will be given a copy of this informed consent form containing my signature and his/her signature.

Doctor (Researcher):

Name_____ Date_____ Signature _____ Tel.: _____