Subject informed consent

Project name: Long-term survival outcome based on primary non-ampulla duodenal adenocarcinoma

Informed consent form version number and version date: V1.0/2024.4.2

Sponsor: Nanfang Hospital, Southern Medical University

Dear Subjects:

We would invite you to participate in a study based on long-term survival outcomes of primary non-ampullary duodenal adenocarcinoma. This study will observe the efficacy and safety of adjuvant therapy, pancreatic invasion and advanced tumor overall survival compared with the long-term survival outcome of primary non-ampullary duodenal adenocarcinoma. This study has been reviewed and approved by Nanfang Hospital, Southern Medical University.

Before you decide whether to participate in this study, please read the following information as carefully as possible to help you understand the study and why it is being conducted, the procedures and duration of the study, and the possible benefits, risks, and discomfort of participating in the study. If you wish, you can ask your doctor for an explanation, or you can discuss it with your family and friends to help you make a decision.

1. Study background

The background of this study is that duodenal adenocarcinoma remains a relatively rare and mysterious entity among GI malignancies, accounting for less than 1% of all GI cancers but more than 50% of small bowel cancers. This rarity has led to a poorly described natural history of the disease and ongoing ambiguity around the optimal management strategy. DA is often compared to colorectal cancer because they share a location in the GI tract and exhibit similar molecular features and potential pathways for tumor development. However, left and right colon cancers have their unique genomic features and clinical presentation, which stem from their specific location in the colon. Therefore, the location of the tumor and its genomic profile are considered to be important factors affecting the prognosis of colorectal cancer and small bowel adenocarcinoma.

The management of primary non-ampullary duodenal adenocarcinoma faces several challenges, including the lack of established guidelines based on scientific evidence worldwide, the difficulty of early detection due to the rarity of the disease and the lack of specific screening markers, and the limited evidence to support various treatment modalities. Surgical resection is the only possible treatment for primary non-ampullary duodenal adenocarcinoma. The complexity of surgery, which often involves pancreaticoduodenectomy, has evolved over the years, and advances in perioperative care and surgical techniques have helped to reduce morbidity and mortality, but long-term survival outcomes have not uniformly improved. Adjuvant therapy, including chemotherapy and radiotherapy, has been explored as a means of improving survival, especially in cases with adverse pathological features, such as lymph node involvement or advanced stage of diagnosis.

2. Study purpose

No randomized controlled trial has been conducted to compare the efficacy of surgery alone with perioperative adjuvant therapy for primary non-ampullary duodenal adenocarcinoma. All of the studies were retrospective comparisons of outcomes between surgery alone and combined surgery, so there may be patient selection bias. Numerous meta-analyses and systematic reviews have delved into the treatment of primary non-ampullary duodenal adenocarcinoma, but most of the studies are retrospective, single-center, and small-sample size series, especially in China.To address this knowledge gap, we conducted a hospital-based cohort study aimed at investigating the long-term prognosis of patients with primary non-ampullary duodenal adenocarcinoma and analyzing the influence of tumor characteristics, surgery, and adjuvant therapy on survival outcomes.

3.Study process

3.1How many people will participate in the study?

This study will be conducted at 1 research center and 400 subjects are expected to volunteer.

3.2 Study duration

The study will last approximately 1 month. It will take you

approximately 1 day to enroll in the study, and you can do so at any time Choose to withdraw from the study without any penalty or loss of any benefits you would otherwise have received. However, if during the course of the study you decide to withdraw from this study, we encourage you to discuss this with your doctor first.

3.3. Study procedure

This is an observational study and we are not doing any therapeutic interventions for you. After entering the study you will continue with your original treatment, your diagnosis and treatment will be judged by your doctor based on regular practice. Information from your routine clinical practice will be collected:

(1) Record demographic data: date of birth, gender, initials;

(2) Medical history and physical examination (including vital signs, height, weight, BMI, physical examination of all systems; HCC Past and present history, etiology);

(3) Clinical manifestations (symptoms, tumor location, diagnosis stage), treatment (surgical intervention, adjuvant therapy treatment) and survival outcome (survival time, recurrence), details of the surgical procedure (scope of resection, lymph node dissection);

(4) Record laboratory test results: including preoperative laboratory values (such as CEA, CA19-9 levels) and can genetic markers used (KRAS mutation, dMMR/MSI-H);

(5) Pathological findings (tumor differentiation, lymphatic vascular infiltration, perineural infiltration) were recorded;No need to come to the hospital during the follow-up period, only telephone follow-up. If you have any concerns about this procedure, please discuss with our researchers. Regarding the procedure of this study, we will follow the following, please carefully consider whether to give you If there is any inconvenience, please let us know immediately.

4.Risk and/or discomfort

There are no risks associated with this study. However, there may be information security risks. We'll do our best.Protect the information you provide from disclosure, however, we cannot guarantee the absolute security of the information. In this study some of the questions we ask you may make you feel uncomfortable and you may refuse to answer such questions.

You can rest at any time during the study. You may opt out of the study at any time during the study.

5. What are the benefits of participating in the study?

Participating in this study may not provide you with a direct medical benefit. But we hope that through your participation there will help expand access to primary non-ampulla duodenal adenocarcinoma for patients with the same condition/disease as you to provide more information for future diagnosis and treatment of the disease.

6. Alternative treatment options

This study will not provide any treatment measures, your diagnosis and treatment will be studied according to the doctor's own judgment, you can continue to maintain the usual treatment plan.

7. Use of research results and confidentiality of personal information at the end of the study

We will analyze the data. You will have the opportunity to be informed of the findings. You may ask your study doctor about the findings and ask them to explain them. The results of this study may also be published in the journal it may be reported at the meeting, but will not contain any information that may identify you.To ensure privacy, your name and other identity will not be attached to records or samples released for research purposes Identify information. Instead, your information will only be identified by a code. Only research doctors and authorized personnel can link this code to your name through a checklist that will be kept securely at the research center.

Sponsor, ethics review committee, if necessary to ensure that research is conducted correctly at the research center the Board and government authorities have access to your data as required, and they are bound by confidentiality obligations and will not violate them your privacy.

You have the right to control the use and disclosure of your personal information. Where permitted by national law, you may feel free to ask to see your medical information. You have the right to see all the letters

collected about you through the research doctor breath and ask for correction.

8. Study new information

During the study period, if there are changes in study procedures, newly discovered side effects, or possible effects on your health or participation the research team will inform you if a major situation arises. The study doctor will inform you immediately and will also work with you discuss whether you want to continue to participate in the study.

9. Study costs, compensation and damages

(1)Research related examination fees

There is no cost to you to participate in this study.

(2)Compensation for participating in the study

You will not receive any compensation for participating in this study

(3)Damages

If impaired as a result of participating in the study, you will receive active treatment by the sponsor Southern Medical University the cost of the treatment provided by the hospital will be compensated in accordance with the law.

10. You may voluntarily choose to participate in the study or withdraw from the study

Participation in the study is entirely voluntary. You may decline to participate in the study, or in the study withdraw from the study at any time during the course will not affect your relationship with your doctor, nor will it affect you the medical care has other aspects of the loss of interest. You will not be discriminated against or treated unfairly, and you will be treated accordingly treatment and rights will not be affected.

Your doctor or investigator may terminate your participation in the study at any time in your best interest

If you do not participate in the study, or drop out of the study, there are many alternative treatments available.You do not have to choose to participate in this study to treat your disease.

If you withdraw from the study for any reason, you may be asked

about your use of the trial method situation. If your doctor deems it necessary, you may be asked to undergo laboratory tests and a physical examination. This protects you is very beneficial to health.

11.Relevant contact information

If you have any questions related to this study, please contact Tao Chen at 020-62786854.

If you have any questions related to your rights/interests, or if you would like to reflect on your participation in this study process or If you have any difficulties, dissatisfaction or concerns, or if you would like to provide comments or suggestions related to this study, Please contact the Medical Ethics Committee of Nanfang Hospital, Southern Medical University at 020-62787238 or Email:nfyyec@163.com.

Informed Consent and Consent signature page

Declaration of consent

I have read the above introduction to this study and have had the opportunity to discuss it with my doctor ask questions. All my questions were answered satisfactorily.

I am aware of the possible risks and benefits of participating in this study. I understand that participating in the study is voluntary, and I do acknowledges that there has been sufficient time to consider this and understands that:

I can always consult the doctor for more information.

I can withdraw from the study at any time without discrimination or retaliation, medical treatment and benefits be affected.

I am also aware that if I withdraw from the study midway through, especially due to medication that causes me to withdraw from the study
If I tell the doctor about the change of my condition and complete the corresponding physical examination and physical and chemical examination, it will be harmful to me and the whole study is very beneficial.

If I need to take any other medication for my illness, I will consult my doctor before hand or tell the doctor afterwards.

I consent to the drug regulatory authority, ethics committee or sponsor's representative having access to my research data.

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

Finally, I decided to agree to participate in the study

Subject's Signature: Date: Contact Number:

Guardian's Signature: Relationship with subject:
(Note: If the subject is unable to sign the informed consent due to lack of/limited capacity or other reasons, it shall be signed by his guardian)

Fair Witness Signature: Date:
Contact number:
(Note: Only if it is possible to include subjects who are informed but unable to read the text, (e.g., illiterate, visual when the witness is in the

know, it is better for the researcher to keep the video material for use Informed evidence).

I have accurately informed the subject of this document, that he/she has accurately read the informed consent form,and demonstrate that the subject was given an opportunity to ask questions and that he/she consented voluntarily.

I confirm that subjects have been explained the details of this trial, including their rights and possible benefits and risk, and give them a signed copy of the informed consent.

Investigator Signature: Date:

Researcher's work phone: mobile number: