Informed Consent Form•Notification Page

Project name: Gastric cancer marker detection and its kit development

Dear Sir/Madam:

We will invite you to participate in a clinical trial study of "gastric cancer marker detection and its kit development".

Before you decide whether to participate in this research, please read the following as carefully as possible. It can help you understand the content of the research, why you want to conduct this research, and the benefits, risks and discomforts that this research may bring to you. This study has been reviewed by the Medical Ethics Committee of the Second Affiliated Hospital of Wenzhou Medical University, and is in compliance with relevant Chinese regulations and the Declaration of Helsinki and other ethical principles that protect the rights and interests of subjects.

Research Introduction

1. Research background

Gastric cancer is a highly malignant tumor of the digestive system, especially in China. It is mostly advanced gastric cancer, and it is one of the tumors with poor prognosis. It is characterized by easy invasion and metastasis, and the rate of recurrence and metastasis after surgery is relatively high. High, five-year survival rate is unsatisfactory, and the results of surgery, radiotherapy and chemotherapy are unsatisfactory. The main reasons are that gastric cancer has fewer autonomic symptoms, lack of specific tumor indicators, and insensitive imaging tests, which are usually difficult to detect early. In addition, due to early metastasis through the microlymphatic system and hematological metastasis, the penetration rate of gastroscopy in China is low, and patients are often in the middle and advanced stages of gastric cancer at the time of admission. The research and exploration of gastric cancer markers and the development of their kits is a very urgent topic, and it is also a current international research hotspot.

2. Research purpose

Research and explore the development of gastric cancer markers and their kits to improve the diagnosis and treatment rate of gastric cancer.

3. What will I need to do if I participate in the research?

If you meet the selection criteria and agree to participate, you will cooperate with the nurse to take blood routines and provide enough gastric tissue samples (including tissue samples obtained by biopsy or surgery).

4. What are the inclusion and exclusion conditions?

Inclusion criteria

- **Patient:**
  - **a) Age greater than or equal to 18 years old (including 18 years old);**
  - **b) Patients who are diagnosed with cancer after pathological diagnosis;**
  - **c) Can provide enough tissue specimens;**
  - **d) Have not received anti-tumor treatment in the past;**
  - **e) Comply with the principle of informed consent, and sign the informed consent form.**
- **2. Healthy people:**
  - **a) Age greater than or equal to 18 years old (including 18 years old);**
  - **b) No underlying disease;**
  - **c) Can provide enough tissue specimens;**
  - **d) Comply with the principle of informed consent, and sign the informed consent form.**

Exclusion criteria

a) **The tumor foci cannot be clearly derived from a specific tumor type;**

b) **Those with a history of other tumors, autoimmune diseases, and allergies;**

c) **Previously received anti-tumor treatments such as surgery, chemotherapy, radiotherapy, molecular targeted therapy, immunotherapy, biological therapy or Chinese medicines with anti-cancer and anti-tumor effects in the instructions;**

d) **Participated in any clinical trial within 90 days before the experiment;**

e) **Received major surgery within 90 days before the experiment;**

f) **Received bone marrow transplantation 90 days before the experiment;**

g) **Subjects who could not complete the study due to other reasons or judged by the investigator to be unsuitable for participating in this study.**

5. If you participate in this study, what benefits will you have?

The valuable information you provide in the research process will facilitate the prevention, diagnosis and treatment of diseases in the future and make important contributions to the cause of human health.

6. What are the risks of my participation in the research?

This project mainly uses your blood samples and stomach tissue samples for research. Tissue specimens. Tissue specimens are sourced from biopsy or post-operative specimens, which are your existing specimens. Participating in this trial will not create adverse risks for you. The main risk of this project comes from the risk of venous blood sampling during routine blood sampling in routine diagnosis and treatment. The common adverse reactions of blood draw include: 1. Bleeding at the needle eye; 2. Local skin allergic reaction; 3. Countermeasures for subcutaneous hemorrhage and local hematoma; 4. Phlebitis. During the trial, some other discomforts may occur. Please tell your research physician immediately, and he/she will deal with your discomfort.

7. Will participating in this study increase my medical expenses?

The tissue specimens required for this study are taken from the specimens you have obtained through biopsy or surgery. In addition, the blood sample required for this study is taken from the remaining blood after your blood routine test, which is required for normal clinical diagnosis and treatment. Therefore, in this study, you do not need to bear other additional costs related to the study, and you will not increase additional medical or testing costs due to participation in this study.

8. What kind of compensation will be provided for participating in this research?

You will not receive any financial compensation for participating in this research.

9. Compensation for damages

In the course of this trial, if you suffer damage and the damage is directly caused by participating in this trial, rather than due to your own disease or non-compliance with the trial regulations, the project team will provide corresponding compensation in accordance with relevant laws and regulations.

10. Is personal information confidential?

If you decide to participate in this study, your personal information and related information about participating in the experiment and in the experiment will be kept confidential. All test results (including personal data, laboratory test documents, etc.) appearing in the original medical records will be kept completely confidential within the scope of the law, and only your initials in pinyin and the number assigned when you participated in the test will appear. In relevant research summaries, articles, and public publications, if necessary, only your initials and number will appear in the pinyin.

When necessary, the drug regulatory department, ethics committee or project funding department can consult the data of the subjects participating in the research according to regulations. However, without permission, they will not use the data of the participants in the study for other purposes or divulge it to other groups.

11. How to get more information?

You can ask any questions about this trial study at any time, you can consult a doctor

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

12. Do I have to participate in this research or can I withdraw halfway?

Whether to participate in this study is entirely up to your volition, and you can refuse to participate in this study. At any time during the research process, you have the right to withdraw from this research. If you refuse to participate or withdraw halfway, your benefits will not be affected, and you will not be discriminated against or retaliated against. If you choose to participate in this study, we hope that you will continue to complete the entire trial process.

Your doctor or investigator may suspend your participation in this trial at any time for your best interests.

13. What should I do now?

Whether to participate in this pilot study is up to you. You can make a decision after discussing it with your family or friends.

Before you make a decision to participate in the trial, please ask your doctor about the relevant questions as much as possible until you fully understand the trial study.

14. Ethics Committee

If you have any dissatisfaction during the study, please contact the Medical Ethics Committee of the Second Affiliated Hospital of Wenzhou Medical University.

Ethics Committee Office: Yaoxi District Ethics Committee Office of the Second Affiliated Hospital of Wenzhou Medical University.

Contact number: 0577-85676879.

Thank you for reading the above materials. If you decide to participate in this trial study, please tell your doctor and he/she will arrange all matters related to the trial for you.

Informed Consent Form

Consent Signature Page

Consent statement

1. I have read this informed consent form, and the person in charge of the project has explained the purpose, content, risks and benefits of this experiment to me in detail;

2. I have discussed and asked related questions about this research, and the answers to these questions are satisfactory to me;

3. I have enough time to make a decision;

4. I voluntarily agree to participate in the clinical research described in this article;

5. I agree to the representative of the drug regulatory department, ethics committee or project funding department to consult my research data;

Finally, I decided to agree to participate in this experimental study and promise to follow the doctor's advice.

Subject’s signature: Date:_____

Subject's contact number:

Signature of legal representative: Date:_____

Relationship with the subject:

Telephone number of legal representative:

I confirm that I have explained to the subject the details of the study, including their rights and possible benefits and risks.

Doctor’s signature: Date:_____

(This page is a necessary part of the subject's informed consent. Each "subject's informed consent" must have the signature and date of the subject or legal representative and the research doctor to be valid.)