
Informed Consent Form for Research Projects

The application of extracellular vesicle detection in gastric juice based on metamaterial sensing in the diagnosis of gastric cancer and related diseases

Institution	Beijing Friendship Hospital, Capital Medical University
Project leader	Li Min
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Project Title: Application of Gastric Juice Extracellular Vesicle Detection Based on Metamaterial Sensing in the Diagnosis of Gastric Cancer Related Diseases

Sponsor: Beijing Friendship Hospital, Capital Medical University

Research Institution: Beijing Friendship Hospital, Capital Medical University

Principal Investigator: Li Min

Respect of subjects: you are invited to participate in a metamaterial sensor based extracellular gastric juice vesicle detection in the diagnosis of gastric cancer and related diseases. Please read this informed consent form carefully and make a decision to participate in the study carefully. When your research physician or researcher discusses the informed consent form with you, you can ask him or her to explain to you any areas that you do not understand. We encourage thorough discussion with your family and friends before making any decision to participate in this study. If you are participating in another study, please inform your research physician or research staff. The purpose, background, research process and other important information of this study are as follows:

1. Background:

The research background of this study is the cancer of the stomach is an important cancer throughout the world, ranked fifth in the global cancer incidence, ranked fourth in the mortality. In fact, most cases of gastric cancer are diagnosed at an advanced stage, with a poor prognosis and limited treatment options. The 5-year survival rate of early gastric cancer is more than 90%, while that of advanced gastric cancer is only about 10%. Therefore, early and accurate endoscopy to reduce mortality and improve prognosis of patients with gastric cancer has important significance. Gastric juices are digestive juices in direct contact with gastric tissue and bypass the metabolic functions of the liver, containing large amounts of shed malignant cells and tumor products, making them potentially ideal biomarkers with satisfactory sensitivity and specificity. In existing research, studies of gastric juice extracellular vesicle rarely involved. Extracellular vesicles, as important components of functional molecules in organisms, play a key role in the development and progression of diseases. By studying the composition of extracellular vesicles in

gastric juice, we can explore their potential role in the development of gastric cancer and find possible biomarkers, so as to provide new clues and evidence for the early diagnosis, prognosis evaluation and treatment strategy of gastric cancer.

2. Objectives:

The purpose of this study is to study the extracellular vesicles in gastric juice under different disease states, to screen out liquid biopsy markers that can be used for the diagnosis of early gastric cancer, and to screen out biomarkers for disease progression or high-risk groups, so as to achieve early disease prediction, guide endoscopic precision examination, and reduce missed diagnosis. This study will be conducted in Beijing Friendship Hospital, Capital Medical University. The diagnosis and treatment of patients undergoing gastroscopy and the analysis of gastric juice samples will further guide the precise endoscopy.

3. Research process:

(1) How many people will participate in the study?

About 100 people will participate in the Beijing friendship hospital affiliated to the capital university of medical sciences, carried out the study.

(2) The research steps:

If you agree to participate in this study, please sign the informed consent.

Inclusion criteria: 1. The patients in the center of the Beijing friendship hospital affiliated to the capital university of medical sciences, endoscopic gastroscopy, and pathological biopsy. 2. No previous history of gastrointestinal cancer.

Exclusion criteria: 1, the patient can't cooperate to check. 2. Previous history of gastrointestinal tumors, gastrointestinal surgery, physical and chemical injuries of the gastrointestinal tract. 3. Severe bile reflux. 4. Take simethicone and other defoaming agents before examination.

You will not do gastroscope examination because only to participate in this study, only in the process of your clinical routine endoscopy to collect related information and gastric juice, about

10 to 20 ml/time, do not need to participate in follow-up.

(3) How long will the study last?

During the study is limited to the endoscopic check, you can opt out at any time without penalty, also won't lose you could have any interest. However, if during the course of the study you decide to withdraw from the study, we encourage you to discuss this with your doctor first.

4. Risk and benefit:

(1) To participate in this study the risk or adverse reaction is what?

You will not do gastroscope examination because only to participate in this study, only collect gastric juice in clinical routine inspection process, about 10 to 20 ml/time. The risks of participating in this study are the same as the informed consent for endoscopy. You should discuss these risks with your study physician, or if you would like to talk to your regular physician who cares for you.

(2) To research what is the benefit?

If you agree to participate in this study, you will not be able to get extra direct medical benefit. We hope that the information gained from your participation in this study will benefit patients with your condition in the future.

5. Will my information be kept confidential?

In you and other participants' understanding and help, through this project research results may be published in medical journals. However, we will keep your research records confidential as required by law. The personal information of the study subjects will be kept strictly confidential. Your personal information will not be disclosed unless required by relevant law. If necessary, government management departments, hospital ethics committees and other relevant researchers can access your data according to regulations.

6. Regarding research expenses and related compensations

There is no research fee or compensation for this study. In the event of damage associated with

the study, you can get by the Beijing friendship hospital affiliated to the capital university of medical sciences, provide necessary medical care, after the approval of relevant units in accordance with the relevant laws of compensation/compensation in accordance with the relevant laws and regulations.

7. Subject rights

The subjects right in the research of the whole process, you are all voluntary. If you decide not to participate in this study, it will not affect the other care you should receive. If you decide to participate, you will be asked to sign this written informed consent form. You have the right to withdraw from the study at any stage without discrimination or unfair treatment, and your corresponding medical treatment and rights and interests will not be affected.

8. Subject responsibility

As a subject, you need to provide the research doctor with truthful information about your medical history and current physical condition; inform the research doctor of any discomfort you experience during this study; do not take any restricted drugs or foods that the doctor has informed you about; and tell the research doctor whether you have participated in other studies recently or are currently participating in other studies.

9. If I have any questions or difficulties, who should I contact?

If you have any questions related to this research, please contact Dr. Li Min at 010-63139288. If you have any questions related to your rights or interests, or if you wish to report any difficulties, dissatisfaction or concerns encountered during your participation in this research, or if you would like to provide any opinions or suggestions related to this research, please contact the Life Ethics Committee of Beijing Friendship Hospital, Capital Medical University. The contact number is 010-63139006.

Researcher's Notification Statement

"I have informed the subject of the research background, purpose, procedures, risks and benefits of the application of metamaterial sensing based detection of extracellular vesicles in gastric juice in the diagnosis of gastric cancer and related diseases. I have given him/her enough time to read the informed consent, discuss with others, and answer his/her questions about the research. I have told the subject to contact Dr. Li Min at any time when he or she has problems related to the study, and to contact the Bioethics Committee of Friendship 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/she can withdraw from the study; I have informed the subject that he/she will be given a copy of this informed consent form containing my signature and his/her signature."

Signature of researcher who obtained informed consent: _____ Date: _____

Informed Consent Statement for Participants

"I have been informed about the background, objectives, procedures, risks and benefits of the study of 'metamaterial sensing based detection of extracellular vesicles in gastric juice for the diagnosis of gastric cancer and related diseases'. I had plenty of time and opportunity to ask questions, and I was satisfied with the answers. I was also told who to contact if I had a question, a difficulty, a concern, a suggestion for the research, or if I wanted further information or assistance with the research. I have read this informed consent form and agree to participate in the study. I knew that I could withdraw from the study at any time during the study without any reason and I was informed that I would be provided with a copy of this informed consent form containing my signature and that of the investigator."

Subject's Signature: _____ Date: _____

Subject's Contact Number: _____

(When the subject's capacity for informed consent is insufficient or lacking, add or replace the following:)

Guardian's signature: _____ Relationship to the subject: _____

Guardian's contact number: _____ Date: _____

Informed Consent Statement for the Storage of Biological Samples and Clinical Information

Do you agree to use the biological samples and related information generated in this study for future research?

☐ I agree for the future research, and authorize Beijing friendship hospital affiliated to the capital university of medical sciences, life ethics committee review to use my sample and information.

☐ I don't agree for the future research.

Donors signature: _____ Date: _____

If the donor is a person without or with limited capacity for civil conduct, the signature and date of the legal representative are required.

Signature of legal representative: (Relationship to donor:) _____

Date: _____

You may change this decision at any time in the future. Please contact Li Min at that time and sign a statement of withdrawal of donation. We will immediately destroy the remaining samples and information as per your request and will no longer use them.