A single center randomized prospective study on the criteria for lymph node sorting for pathological examination after curative surgery for gastric cancer

（DJY001 Trail）

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Informed Consent Form

Dear participants:

It's our honor to invite you to participate in a clinical trial of lymph node sorting from gastric cancer sample in operation, which is named as "The Criteria for Lymph Node Sorting for Pathological Examination in Gastric Cancer". We wish you to read carefully this informed consent form, and then to make a deliberate decisions on whether to participate in this clinical trial. You can ask your research doctor about anything related to this clinical trial that you don't understand. The research doctor will answer your questions until you are satisfied. In addition, you had better ask for advice from your relatives or friends before you make the final decision to participate in this clinical trial. If you have taken part in other clinical trials, please tell your research doctor.

The main contents of this clinical trial are as follows:

What is the aim of clinical trial?

The aim of this clinical trial is to elucidate the impact of the different lymph node sorting methods on the migration of the pTNM classification for gastric cancer, which can provide the direct proofs to evaluate the optimal lymph node sorting method to obtain the accurate pTNM classification after curative surgery. The research programme and the informed consent have been approved by the ethics committee of the Tianjin cancer Institute and Hospital.

How many people will be recruited in this study?

This study is a clinical validation study based on the Tianjin cancer Institute and Hospital. A total of 278 people will be recruited in this study.

What are the prerequisites for patient's participating in this study?

Firstly, you must sign this informed consent, representing you are volunteered to participate in this study. Furthermore, you must meet the recruited criteria of this study. They are as follows: no pregnancy, no history of other malignancies, no history of gastric cancer surgery or the neoadjuvant therapy.

Research process

The study mainly collected specimens from two groups of people, including patients with gastric cancer confirmed by the histopathological examination and with potentially curative gastrectomy by the preoperative assessment. After patients sign the informed consents, research doctor will randomly allot the patients into fine lymph node sorting group or regional lymph node sorting group.

Is there any risk to participate in this study for patients?

This study is a non - intervention clinical trial that does neither interfere with your diagnosis and treatment nor damage your social relationship.

What are the advantages to patients for participation in this study?

This clinical trial can evaluate a reliable method for patients to exactly estimate the lymph node metastasis after curative gastrectomy, which may make an important contribution to precisely predict the prognosis.

Is there any cost for the patient to participate in this clinical trial?

No extra cost need to be paid by patients for participation in this clinical trial, with the exception of diagnostic and therapeutic costs of patients.

What is the confidentiality for patients in this clinical trial?

We guarantee that there will never be any personal identification of your information in the research results, even if the research manuscript will be published in a journal. The research materials and specimens will be stored in the research hospital with the special person responsible for the custody. However, the bidding unit, the state food and drug administration and the ethics committee have the right to consult the subject's information. If you agree with the specimens applied to other medical trials by researches involved directly in the studies, we will promise that your personal identification information can not be contained in any datum or document.

What are the rights of the patients participated in this trial?

As your participation is voluntary, you may have the right to withdraw from this clinical trial at any time.

Who can explain the inquiries for patients by telephone when they have problems?

If you have any question related to this clinical trial, please directly contact the director of the research center who named as Jingyu Deng.

The telephone number of Dr. Deng is 86-22-23340123-1061.

The telephone number of ethics committee approved this clinical trial is 86-22-23524155.

Informed Consent Signature Page

Research Title: A single center randomized prospective study on the criteria for lymph node sorting for pathological examination after curative surgery for gastric cancer

As a participant, I have read the above information and understand the purpose and the potential benefits of participating in this clinical trial. All the questions I put forward on the research procedure and the research content have been answered with my satisfaction. I agree to send all lymph nodes from the specimens of gastric cancer by regional sorting method or fine sorting method to pathologically confirm the metastasis and to apply to other related studies. I voluntarily signed this informed consent and volunteer to participate in this clinical trial.

Signer's signature: Date of signature:
Signature by legal agent (if necessary): Date of signature:
Witness signature (if necessary): Date of signature:

We have read and explained the informed consent to the subject, and then answered all the questions he/she has raised. Him/herself has also already understood and agreed to participate in the scientific research.

Signatures of researchers: Date of signature: