A clinical prospective study to validate a risk scoring model integrated preoperative immune-inflammatory indicators, tumor markers and imaging examination for the lymph node metastasis of gastric cancer before surgery

（DJY004 Trail）

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Research Institute： Cancer Hospital & Institute of Tianjin Medical University

Informed Consent Form

Dear participant:
We are delighted to extend an invitation for your to participate in a clinical trial focusing on the risk prediction of lymph node metastasis in patients with gastric cancer before surgery. The study is titled " A clinical prospective study to validate a risk scoring model integrated preoperative immune-inflammatory indicators, tumor markers and imaging examination for the lymph node metastasis of gastric cancer before surgery". Before making a decision, we kindly urge you to carefully review this informed consent form. If you have any questions about the trial, you can consult your research doctor. They will be dedicated to addressing your concerns until you are satisfied. Additionally, we recommend seeking advice from your relatives or friends before finalizing your decision to participate. If you have previously participated in other clinical trials, please inform your research doctor.

What is the aim of clinical trial?
The primary aim of this clinical trial is to assess the clinical applicability of our scoring model in predicting the risk of lymph node metastases in patients with gastric cancer before surgery. By doing so, we aim to provide a warning assessment system that can potentially be beneficial in early identification of lymph node metastases and to guide the modification of clinical follow-up strategies based on the risk predicted by our scoring model. The research program has obtained approval from the ethics committee of the Tianjin Cancer Institute and Hospital, ensuring compliance with ethical standards.

How many individuals will be enrolled in this study?
This study, conducted at the Tianjin Cancer Institute and Hospital, is a clinical validation study. At least 100 individuals will be recruited to participate in this research.

What are the requirements for patients to participate in this study?
Firstly, it is necessary for you to provide your voluntary consent by signing the informed consent form in order to participate in this study. In addition, you must meet the specific inclusion criteria as follows: Primary gastric adenocarcinoma, Radical surgery (Radical degree must be R0, except palliative surgery, distant metastatic cases), no autoimmune, inflammatory, or blood diseases, prior or concurrent without other cancers, no active infection and inflammation, no active bleeding, no history of neoadjuvant chemoradiotherapy, no history of blood transfusion, corticosteroids, and white-cell-boosting drugs 1 month before blood drawing.

Research process
(1) Eligible patients will be enrolled based on the inclusion criteria.
(2) Detailed clinicopathological information of all patients will be recorded, and regular postoperative follow-up will be conducted.
(3) The study will analyze the concordance between the actual occurrence of lymph node

metastases determined through pathological examination and the predicted results obtained from the risk scoring model. This analysis aims to evaluate the clinical applicability of the model.

Are there any potential risks for patients who participate in this study?
This study is a non-interventional clinical trial that will not interfere with your diagnosis and treatment for gastric cancer, nor will it negatively impact your social relationships.

What benefits do patients gain from participating in this study?
This study is purely observational and will not directly impact the participants' clinical outcomes. However, the results of this study could potentially serve as a valuable theoretical foundation for making informed and favorable clinical decisions in the future, benefiting patients overall.

Are there any expenses involved for patients participating in this clinical trial?
Patients do not need to bear any additional costs for participating in this clinical trial, except for the diagnostic and therapeutic expenses that are typically associated with their condition.

How are patient confidentiality and privacy protected in this clinical trial?
In this clinical trial, we ensure that your personal information will remain confidential and protected. Your data will be anonymized in the research results and any publications. The research materials will be securely stored by a designated person at the research hospital. However, it is important to note that the state food and drug administration, and the ethics committee have the right to access participant information for consultation purposes. Additionally, if you consent to the use of your materials in other medical trials conducted by the researchers directly involved in the study, your personal identification information will not be included in any data or documentation.

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 clinical prospective study to validate a risk scoring model integrated inflammatory indicators, tumor markers and imaging examination for the lymph node metastasis of gastric cancer before surgery.

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 the use of my relevant clinicopathological information for medical scientific 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: