A clinical prospective study to validate a risk scoring model for the hepatic metastases from gastric cancer after curative surgery

（DJY003 Trail）

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Informed Consent Form

Dear participants:

It's our honor to invite you to participate in a clinical trial of on the risk prediction of hepatic metastasis in patients with pathologically confirmed gastric cancer after curative surgery, which is named as "A clinical prospective study to validate a risk scoring model for the hepatic metastases from gastric cancer after curative surgery". 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 study is to evaluate the clinical applicability of our scoring model for predicting the risk of hepatic metastases from gastric cancer after curative surgery, thereby providing a potentially beneficial warning assessment system to prevent and control the occurrence of postoperative hepatic metastases and to guide the modification of clinical follow-up strategies. In addition, the impact of neoadjuvant treatment and its efficacy on the risk and interval of hepatic metastases after curative surgery in patients with gastric cancer will be analyzed. 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 120 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: Undergone curative gastrectomy plus D2 lymph node dissection, postoperative pathology confirmed gastric cancer with pM0, no hepatic tumors or other occupying diseases prior to curative surgery, no chronic diseases such as cirrhosis and hepatitis, no hepatic schistosomiasis, no hepatic bilharzia, no hepatic tuberculosis, no severe fatty liver, no history of abdominal chemotherapy, no other serious concomitant diseases, no history of other malignancies.

Research process

(1) Patients meeting the inclusion criteria will be enrolled;

(2) Clinicopathological details of all patients will be recorded and regular postoperative follow-up will be conducted;

(3) The consistency between the actual results of postoperative hepatic metastases

occurrence and the predicted results by the risk scoring model will be analyzed to identify the clinical applicability of the model, not only for patients not receiving preoperative neoadjuvant therapy, but also for those receiving such therapy;
(4) The impact of neoadjuvant therapy and its efficacy (TRG0-1 vs TRG2-3) on the risk and interval of postoperative hepatic metastases will be further explored.

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 for gastric cancer nor damage your social relationship.

What are the advantages to patients for participation in this study?
This is an observational study and will not make a difference to the participants' clinical course, however, the findings of this study may provide a theoretical basis for making favourable clinical decisions for patients in the future.

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 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 materials 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 clinical prospective study to validate a risk scoring model for the hepatic metastases from gastric cancer after curative 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: