Cover page

Trial Title:

A New Conception About Individualized Treatment Allocation for HCC—Using Machine Learning

Unit of Study: The Second Affiliated Hospital of Air Force Military Medical University

Principal Investigator：Lei Liu

Date: 2023-8-20

NCT number and document date have not been assigned

Informed Consent Form

Protocol Name: A New Conception About Individualized Treatment Allocation for HCC —Using Machine Learning

Main researchers:
Jun Zhu, Enxin Wang, Shoujie Zhao, Shouzheng Ma, Ying Han, Hong Han, Lei Liu
Sponsor: Professor: Liu Lei

Dear Subjects,

You are invited to participate in the 'A New Conception About Individualized Treatment Allocation for HCC', which was supported by Professor Lei Liu. Please read this informed consent form carefully and make careful decisions about whether to participate in this study. Participation in this study is entirely your choice. As a subject, you must give your written consent before joining a clinical study. When your research doctor or researcher discusses consent with you, you can ask him or her to explain to you what you don't understand. We encourage you to have a thorough discussion with your family and friends before making the decision to participate in this study. You have the right to refuse to participate in the study and to withdraw from the study at any time without penalty or loss of your rights. If you are participating in another study, please let your research doctor or researcher know. The background, purpose, research process and other important information of this study are as follows:

1. Backgrounds

Liver resection (LR) and transarterial chemoembolization (TACE) are the two mainstream treatment modalities for liver cancer patients. According to the European Society for the Study of the Liver and the American Society of Hepatology, patients with satisfactory liver function and performance scores and single tumors or multiple tumors

(fewer than 3 in number, maximum diameter of 3 cm) are recommended for LR According to the Barcelona liver cancer guidelines, patients with unresectable stage A and B are recommended to be treated with hepatic arterial chemoembolization.Another widely used guideline is the staging of liver cancer in Hong Kong (HKLC), which recommends that patients with early and intermediate stages of Child Pugh stage A should consider liver resection, while patients with intermediate and locally advanced tumors of Child Pugh stage B are ideal candidates for TACE. However, it is consistent that people with intrahepatic lesions and no vascular invasion or extrahepatic spread are candidates for TACE and LR. Although medium-stage liver cancer is an ideal population for TACE, a growing body of literature suggests that the postoperative survival benefit of LR is more pronounced than that of TACE. Given the current potentially controversial and vague guideline recommendations, a new, highly effective individualized option for LR and TACE regimens needs to be developed and validated.

To address current issues, we aim to develop and validate prognostic models for localized HCC, integrating LR and TACE treatment into one prognostic model. The model can provide patients with two different sets of prognostic assessments to guide patients in choosing an individualized treatment plan.

2. Aims of study

The purpose of the study is to establish and validate a new artificial intelligence prognostic model by using the basic clinical features, liver function data, tumor burden data and other clinically important prognostic indicators, aiming to guide patients to choose hepatic resection treatment or hepatic artery chemotherapy tethering therapy.

3. Study process

3.1 How many people will participate in the study

Answer: Approximately (5000) people will participate in this study conducted at 15 different research institutes/medical institutions, and approximately (500) people will participate in this study at this hospital.

3.2 What you need to do

1. Before you are enrolled in the study, your doctor will take and record your medical history and perform screening imaging tests such as CT. Baseline data such as your age, gender, etiology, blood biochemistry and tumour load will be collected for this study.

2. After you are confirmed to be eligible for the study, you will be followed up by telephone once every 6 months.

3.3 How long will the study last

You may choose to withdraw from the study at any time without losing any benefits that you would otherwise receive. However, if you decide to withdraw from the study midway through the study, we encourage you to talk to your doctor first. If you have a serious adverse event or if your study doctor feels that it is not in your best interests to continue to participate in the study, he/she may decide to withdraw you from the study. The sponsor or regulatory body may also terminate the study for the duration of the study. However, your withdrawal will not affect your normal medical treatment and entitlements. If you withdraw from the study for any reason, you may be asked about your participation in the study. You may also be asked to undergo laboratory tests and a physical examination if your doctor deems it necessary.

3.4 information and biological specimens collected in the study

In this study, you only need to be active for regular outpatient check-ups and no special blood draws or laboratory tests are required.

4. Risks and benefits

4.1 What are the risks of participating in this study?

The risks that may be associated with your participation in this study are listed below. You should discuss these risks with your study doctor, or if you wish, with the doctor who looks after you on a regular basis.

1) Risks due to progression of the disease itself

2) Recurrence of the tumor

3) Risks associated with the use of post-operative chemotherapy drugs etc.

4.2 What are the benefits of participating in the study?

Potential benefit: We hope that the information gained from your participation in this study will benefit you or patients with your condition in the future, contributing to the construction of personalized treatment plans for liver cancer.

5 Use of research results and confidentiality of personal information

With your understanding and assistance and that of other subjects, the results of research through this project may be published in medical journals, but we will keep your research records confidential as required by law. The personal information of research subjects will be kept strictly confidential and your personal information will not be disclosed except as required by relevant legislation. If necessary, government authorities and hospital ethics committees and other relevant researchers may have access to your information as required.

6 Subjects' Rights and Related Precautions

6.1 your rights

Your participation in the study is voluntary throughout its duration. If you decide not to participate in this study, it will not affect the other treatments 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 trial at any stage without discrimination or unfair treatment and your medical treatment and rights will not be affected.

6.2 Precautions

As a subject, you are required to provide truthful information about your medical history and current medical condition; tell the study doctor about any discomfort you have noticed during this study; refrain from taking restricted medications, foods, etc. that your doctor has informed you of; and tell the study doctor if you have recently participated in other studies or are currently participating in other studies.

7 Contact details for obtaining information

Your doctor will inform you promptly if there is any important new information during the course of the study that may affect your willingness to continue to participate in the study. If you have any questions about your research data, or if you wish to know the findings of this study after it has been completed. You can ask any questions you may have about this study at any time and have them answered accordingly by contacting Research Fellow Zhu Jun on +86 15090331721.

The Ethics Committee has reviewed and approved this study. If you have any questions regarding your rights/interests, or if you would like to reflect any difficulties, dissatisfaction or concerns you have encountered during your participation in this study, or if you would like to provide comments and suggestions related to this study, please contact the Ethics Committee of Xi'an Tangdu Hospital at 029-84777777, email: tdwww.fmmu.edu.cn

Subjects' signature page

Informed Consent Statement:

I have been informed of the purpose, background, process, risks and benefits of this study. I was given sufficient time and opportunity to ask questions and the questions were answered to my satisfaction.

I have also been told who to contact if I have questions, want to reflect on difficulties, concerns, suggestions for the study, or want further information or help with the study.

I have read this informed consent form and I agree to participate in this study.

I am aware that I can choose not to participate in this study or withdraw from this study at any time during the study without any reason.

I have been informed that if my condition gets worse, or if I have a serious adverse event, or if my study doctor feels that it is not in my best interest to continue to participate in the study, he/she may decide to withdraw me from the study. The funder or regulator may also terminate the study for the duration of the study without my consent. If this happens, I will be informed promptly by my doctor and the research doctor will discuss my other options with me.

I will be given a copy of this informed consent form, which contains my signature and that of the investigator.

Subject's signature: _____ Date: _____

(Note: If the subject is incapacitated/limited, the signature of the legal representative and the date of signature are required)

Signature of legal representative: _____ Date: _____

Signature of Independent Witness: _____ Date:_____

Signature of researcher: _____ Date:_____