Informed Consent Form

Study Title: A Prospective, Multicenter, Randomized Controlled Phase III Observational Study on the Impact of Laparoscopic Exploration Staging on the Prognosis of Patients with Clinical Stage III Gastric Cancer

Tianjin Medical University Cancer Institute & Hospital

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Informed Consent Form

Dear Patient:

Hello! We are conducting a study titled "A Prospective, Multicenter, Randomized Controlled Phase III Observational Study on the Impact of Laparoscopic Exploration Staging on the Prognosis of Patients with Clinical Stage III Gastric Cancer" (Protocol No.: CGCA202501). This study is initiated by Tianjin Medical University Cancer Institute & Hospital, with Professor Liang Han from the Department of Gastric Oncology serving as the Principal Investigator. Multiple hospitals across the country are participating. Currently, this study has been reviewed and approved by the Ethics Committees of each participating center. We sincerely invite you to consider participating in this study.

Before you decide whether to participate, please read the following content carefully. If you have any questions, please feel free to ask the study doctor, who will provide detailed answers.

1. Research Project Background and Purpose:

This study aims to compare, through a multicenter randomized controlled design, patients who undergo laparoscopic exploration staging before treatment (experimental group) with patients who receive treatment directly based on imaging findings (control group). The goal is to determine the impact of precision treatment, guided by laparoscopic exploration staging, on the 3-year overall survival (OS), surgical conversion rate, and peritoneal metastasis rate in patients with clinical stage III gastric cancer, thereby providing a scientific basis for precise staging and treatment decisions for gastric cancer.

2. Content and Procedures of Participation:

Enrollment Assessment: If you agree to participate in this study, we will perform a series of examinations to confirm whether you meet the inclusion criteria, including:

Pathological confirmation of gastric adenocarcinoma (including gastroesophageal junction cancer), with histological or cytological evidence.

Gastric biopsy to determine status of Her2, MMR, CPS (PDL1) score, Claudin18.2, and other markers.

Contrast-enhanced CT / endoscopic ultrasound / MRI to confirm clinical stage as cT3/4aN+ (AJCC 8th edition staging criteria), and no evidence of peritoneal metastasis on imaging other than laparoscopic exploration.

Your age must be between 18 and 75 years old, male or female.

ECOG performance status score must be 0-2 (fully active to ambulatory and capable of self-care, but unable to work).

Expected survival ≥ 3 months, with good cardiopulmonary function reserve and no contraindications for anesthesia.

You must voluntarily participate in this study and sign the written informed consent form.

2.1Randomization: If you meet the inclusion criteria, you will be randomly assigned to either the experimental group or the control group in a 1:1 ratio. Randomization will be stratified by the study center using a random table method. You and the doctor cannot choose the group assignment, which is to ensure the impartiality of the study results.

2.2Treatment Plan:

2.2.1Experimental Group: Will undergo laparoscopic exploration.

If peritoneal metastasis (CY+ or P+) or cT4aN+ or cT4bN+ or M1 is found, recommendations include: Systemic therapy + NIPS ± HIPEC or HIPEC.

If no metastasis is found, systemic neoadjuvant therapy is recommended.

Ultimately, each center will determine the specific drug treatment plan and surgical plan based on current guidelines (CSCO, CACA) and their own experience. You may also participate in various drug clinical trials based on your actual situation.

2.2.2Control Group: Will not undergo laparoscopic exploration. Systemic therapy will be recommended directly based on imaging staging. Each center will determine the specific drug treatment plan and surgical treatment plan based on current guidelines (CSCO, CACA) and their own experience. You may also participate in various drug clinical trials based on your actual situation.

2.3 Follow-up: Regardless of which group you are assigned to, follow-up is required according to the following schedule:

Treatment Period: Before each treatment cycle, physical examination, complete blood count, liver and kidney function tests, tumor marker (CEA/CA19-9) tests, and recording of treatment adverse reactions are required.

Within 1 month after surgery / end of treatment: Baseline CT/MRI (chest/abdomen/pelvis) examination, wound healing assessment, etc., are required.

Follow-up Period, Years 1-2: Every 3 months, clinical examination and tumor marker tests are required; every 6 months, a chest and abdominal CT scan is required, and symptoms of recurrence and metastasis are assessed.

Follow-up Period, Years 3-5: Every 6 months, clinical examination and tumor marker tests are required; annually, a chest and abdominal CT scan is required, and survival status is confirmed.

3. Potential Benefits of Participation:

3.1Your condition will receive standardized treatment and close monitoring, helping to detect changes in your condition promptly and adjust treatment plans accordingly.

3.2This study may provide new evidence for the treatment of gastric cancer, improving treatment outcomes and prognosis for future gastric cancer patients.

4. Risks and Discomforts Associated with Participation:

4.1Risks Related to Laparoscopic Exploration (Experimental Group Only): Laparoscopic exploration may lead to complications such as bleeding, infection, or bowel perforation, with an incidence rate of approximately 1-2%. Should these occur, the doctor will take appropriate treatment measures promptly.

4.2Risks Related to Treatment: Regardless of whether you are in the experimental or control group, treatments received may involve chemotherapy-related adverse reactions such as nausea, vomiting,

hair loss, and bone marrow suppression. Immunotherapy or targeted therapy may also lead to corresponding adverse reactions. Doctors will monitor closely and provide symptomatic management.

4.3Inconvenience Related to Follow-up: The follow-up process may require a certain amount of your time and effort, and traveling to the hospital may cause some inconvenience.

5. Privacy:

5.1During the study, your clinical data, examination results, treatment records, and other information will be collected. This information will be entered into the Medidata Rave system via electronic case report forms (eCRF).

5.2We will retain all of your preoperative CT images, high-definition images of peritoneal metastasis sites during surgery (according to Peritoneal Cancer Index (PCI) scoring requirements, images from 13 regions where metastasis is found will be retained). The entire surgery must be video recorded, and the unedited video files will be saved.

5.3We will strictly protect your personal privacy. All data and samples will be anonymized and used only for statistical analysis and related research purposes of this study. Your personal information will not be disclosed to individuals outside the research team unless required by law or regulation.

If you decide to participate in this study, your participation and personal data during the study will be kept confidential. Your medical records will be kept in the hospital. To ensure the study is conducted properly, government regulatory authorities or members of the Ethics Committee may, as permitted by regulations, access your personal data at the study site. Any public report regarding the results of this study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical information within the limits permitted by law. At any time, you may request access to your personal information and have it modified if necessary.

By signing this informed consent form, you agree to the use of your personal and medical information for the purposes described above. Your records will be kept in the archives of Tianjin

Medical University Cancer Institute & Hospital and will be accessible only to research personnel.

When the results of this study are published, your personal medical information will not be disclosed.

6. Your Rights:

6.1Right to Voluntary Participation: Your participation in this study is entirely voluntary. You have the right to withdraw from the study at any stage without affecting your subsequent routine treatment.

6.2Right to Information: During the study, you have the right to be informed about the progress of the research and information relevant to your condition.

7. Ethics Committee Contact Information:

If you have questions regarding the rights of research subjects or wish to provide opinions or suggestions related to this study, please contact the Principal Investigator, Professor Jin Peng, at Tel: [022-23340123 ext. 1061]. You may also contact the Ethics Committee of Tianjin Medical University Cancer Institute & Hospital at Tel: [022-23340123 ext. 6417].

Subject's Informed Consent Signature Page

I have read and understood the above Informed Consent Form and understand the purpose of the study, as well as the potential benefits and risks of participation. The researcher has explained the medical terms in a clear and understandable manner. I have had the opportunity to ask questions, and all my questions have been answered in a way I can understand. I may choose not to participate in this study or withdraw at any time by notifying the responsible doctor, and my medical treatment and rights will not be affected. The responsible doctor may terminate my participation in this study if I require other treatment, fail to adhere to the study plan, experience a study-related injury, or for any other reason.

I have read the above Informed Consent Form, received a copy, and my doctor has provided a detailed explanation. I voluntarily agree to participate in this clinical trial. I agree that relevant parties may review my original medical records to verify the data collected in the study.

Subject's Name (Print): _____ Subject's Phone: _____

Subject's ID Number: _____ Date: Year _____ Month _____ Day _____

(Or)

Legal Representative's Name (Print): _____ Legal Representative's Phone: _____

Date:Year _____ Month _____ Day _____

(Note: Legal representative signature is required if the subject is unable to sign personally.)

I confirm that I have explained the relevant contents of this clinical trial to the patient in detail, including the potential benefits and risks.

Responsible Doctor's Name (Print): _____ Phone: _____

Date: Year _____ Month _____ Day_____