Informed Consent · Informed Notification page

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Dear patient：

You have been diagnosed with_____.We are currently carrying out research and will perform robotic radical gastrectomy or laparoscopic radical: **Safety and feasibility between Robotic and laparoscopic D2 radical total gastrectomy for locally advanced gastric cancer(NCT03500471)**.**Robotic-assisted or laparoscopic gastrectomy** to treat your disease according to your will. The clinical study protocol has been submitted to the Medical Ethics Committee of Southwest Hospital for review and approval.

Before you decide whether or not to participate in this clinical study, please read the following as carefully as possible.It can help you understand the clinical study, why the clinical study was conducted, the procedure and duration of the study.If you wish, you can discuss it with your relatives, friends, or ask your doctor for an explanation to help you make a decision.

1、Clinical background and purpose

1.1 Current status of disease treatment: Although many advances have been made in treatment, radical surgery is still the main treatment method for the gastric. At present, total gastrectomy with D2 Lymphadenectomy is the standard surgical method for advanced gastric cancer such as upper stomach and esophagogastric junction carcinoma. The surgical methods can be divided into open surgery and minimally invasive surgery. Minimally invasive surgery has the advantages of less trauma, less bleeding, less postoperative pain, faster recovery, less complications and so on. It has been widely used at home and abroad and achieved good clinical results. Minimally invasive surgery includes laparoscopic surgery and robotic surgery.

1.2 Objective: In this study, A prospective cohort study was conducted to compare and observe the differences between robotic-assisted radical gastrectomy and laparoscopic surgery for advanced gastric cancer in terms of surgical efficacy and postoperative complications. Therefore, the safety and efficacy of the operation were evaluated scientifically, providing evidence based medicine for its extensive development.

1.3 Your current treatment options: Radical gastrectomy is the main method for the treatment of advanced gastric cancer, and the surgery should meet the requirements of D2 radical gastrectomy. At present, the minimally invasive surgical methods you can choose include robotic-assisted D2 radical gastrectomy and laparoscopic D2 radical gastrectomy.

2、Who should not participate in a clinical study

1.Patients with early gastric cancer；

2.Age<18 years or Age>80 years；

3. radical total gastrectomy with D2 Lymphadenectomy is not required；

4..Enlarged or bulky regional lymph node (diameter over 3cm) supported by preoperative imaging including those surrounding important vessels

5.Emergency surgery due to complication (bleeding, obstruction or perforation) caused by gastric cancer Previous upper abdominal surgery (except laparoscopic cholecystectomy)

6.Previous neoadjuvant chemotherapy or radiotherapy

7.Unstable myocardial infarction, angina, or cerebrovascular accident within the past 6 months

8.FEV1＜50% of predicted values

9.Other malignant diseases

10.Severe mental disorder

11.Women during breast-feeding or pregnancy

3、What will you do if participate in a clinical study?

1． A total of 150 people will be included in this study for 3 years. Before you are enrolled in the clinical study, the doctor will ask and record your medical history, and perform blood routine examination, Blood biochemistry, Serum tumor markers, gastroscopy, upper abdominal CT and other examinations. If you meet the inclusion and exclusion criteria, you may voluntarily participate in the clinical study and sign an informed consent form.

If you do not wish to participate in the clinical study, we will treat you as you wish.

2. If you volunteer to participate in the clinical study, you will follow the following steps：

1) You have accepted our initial screening after admission and are a candidate for inclusion in this clinical study. We will inform you and your family members of the details of this clinical study in detail and answer all your questions. Please sign the informed consent for this clinical study after you confirm that you are fully informed of all the contents of this clinical study.

2) At the same time, you will be asked to fill in detailed personal information. We will make every effort to protect the privacy of your personal information within the scope permitted by law.

3) According to the medical operation routine, decide whether to adopt robotic-assisted radical gastrectomy or laparoscopic radical gastrectomy according to your will. You and your family will be informed and signed the informed consent for surgery.

4) After the operation, we will carefully observe and record your recovery, and inform you or your family members of your condition in time. At the same time, we also need your cooperation to complete some necessary examinations.

5) After the operation, we will further determine whether you will receive chemotherapy according to the pathological diagnosis. During this period, we will carefully observe and record your various symptoms and signs, and actively deal with your various post-chemotherapy discomfort.

6) Postoperative follow-up plan: The first follow-up will be conducted 1 month after the operation. The follow-up doctor will perform physical examination, and the related laboratory tests mainly include blood routine examination, Blood biochemistry, Serum tumor markers, etc. If necessary, upper abdominal enhanced CT examination, chest X-ray examination, gastroscopy examination, etc. At the same time, the postoperative quality of life was assessed by international standards EORTC QLQ-C30 V 3.0 and EORTC QLQ-STO22.

3. Other matters that require your cooperation

You should go to the hospital according to the appointment of the doctor and you (during the follow-up period, the doctor may call or visit you to learn about your situation).Your follow-up is important because your doctor will determine whether the treatment you are receiving is really working and will guide you in a timely manner.

If you need additional treatment, please contact your doctor.

4、Possible benefits of participating in this clinical study

You will not benefit from this study, but the relevant data and information obtained from this study will provide a more reliable evidence-based medical basis for the treatment of delayed gastric cancer with total gastrectomy to benefit future patients.

5、Possible adverse reactions, risks and inconveniences of participating in this clinical study

We will enter the robotic or laparoscopic group as you wish.The possible risks, adverse reactions, and

various surgical complications of the patients in any surgical group cannot be completely prevented by the current medical level, and we will inform them in detail in the form of surgical informed consent before surgery.

If you experience any discomfort, deterioration of illness, or any unexpected situation during the clinical study, whether related to surgery, you should inform your doctor promptly, who will make a judgment and give appropriate medical attention.

You should go to the hospital on time, which takes up some of your time, but also may cause trouble or inconvenience to you.

6、Terms for expenses and damages

1. expenses

Both of the two surgical methods are commonly used in clinical practice. Follow-up is also required in routine medical treatment, and the corresponding costs should be borne by you.

The possible cost of laparoscopic surgery is about ¥90,000, and that of robotic surgery is about ¥110,000. If there are complications related to surgery and anesthesia, the treatment costs will increase.

Postoperative follow-up and examination items were all routine items after gastric cancer surgery, and the costs should be paid by the patients themselves.

We will provide you with health consultation related to gastric cancer, physical examination and quality of life evaluation according to the follow-up requirements, and may give you follow-up by phone or letter.

You need to pay for the treatment and examination of other diseases you have combined.

2. **Injury compensation clause**

If there is any damage related to this study, we will compensate in accordance with the relevant requirements of relevant laws and regulations of the people's Republic of China (the operation risk of the two operation methods is not considered as the research risk of this study)。

7、Is personal information confidential?

Your medical records (surgical records, examination results, etc.) will be completely kept in the hospital. The doctor will record the test results on your medical record. The surgeon and ethics committee will be allowed to access your medical records. Any public report on the results of this clinical study will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical data to the extent permitted by law.

8、How to get more information?

You can ask any questions about this clinical study at any time and get the corresponding answers.

If there is any important new information during the clinical study that may affect your willingness to continue to participate in the clinical study, your doctor will inform you in time.

If you have any questions about the procedure of this study, you can consult **Dr. Li Pingang** at **(023) 68754167**. If you have any questions about your rights and interests to participate in this study, you can consult **the ethics committee of southwest hospital of China** at **(023) 68754814**.

9、Voluntarily choose to participate in clinical research and withdraw from clinical research

Whether to participate in the clinical study depends entirely on your wishes. Participation in this study will not have any therapeutic impact on you. You may refuse to participate in this clinical study or withdraw at any time during the clinical study, which will not affect the relationship between you and the doctor, nor will it affect the loss of your medical treatment or other interests.

For your best interests, the doctor or surgeon may suspend you from continuing to participate in the clinical study at any time during the clinical study.

This test will be aborted or withdrawn if:：

1. Patients intraoperatively/postoperatively confirmed as T4b.

2. tumor confirmed intraoperatively or postoperatively: distant metastasis only found by intraoperative exploration or postoperative pathological biopsy or a positive postoperative peritoneal lavage cytology examination.

3.Requirement of simultaneous surgery for other diseas.

4.Patients intraoperatively confirmed as unable to complete D2 lymph node dissection/R0 resection due to tumor: unable to complete R0 resection due to regional lymph node integration into a mass or surrounded with important blood vessels, which cannot be resected.

5.Sudden severe complications during the perioperative period (intolerable surgery or anesthesia), which renders it unsuitable or unfeasible to implement the study treatment protocol as scheduled.

6.Patients who voluntarily quit or discontinue treatment for personal reasons at any stage after inclusion in this study.

7.Treatment implemented is proven to violate study protocol.

If you withdraw from the clinical study for any reason, you will proceed to the next step under the guidance of your doctor.

10、What should you do now?

Whether to participate in this clinical study is up to you (and your family).

Before you make a decision to participate in the clinical study, please ask your doctor as many questions as possible.

Thank you for reading the above materials. If you decide to participate in this clinical study, please tell your doctor and he / she will arrange all matters related to the clinical study for you. Please keep this information.

Informed consent· Signature page

（Date of edition：2018.01.08）

Title of clinical study：Safety and feasibility between Robotic and laparoscopic D2 radical total gastrectomy for locally advanced gastric cancer:A prospective cohort study

Declaration of consent:

I have read the above introduction about this clinical study, and have the opportunity to discuss and ask questions with doctors about this clinical study. All my questions were answered satisfactorily.

I know the possible risks and benefits of participating in this clinical study. I know that participating in the clinical study is voluntary. I confirm that I have had enough time to consider this and understand that:

I can always ask the doctor for more information.

I can withdraw from this clinical study at any time without discrimination or retaliation, and my medical treatment and rights will not be affected.

I also know that if I withdraw from clinical research halfway, I will tell the doctor about the changes of my condition and complete the corresponding physical and chemical examination, which will be very beneficial to the whole condition.

If I need to take any other treatment due to the change of my condition, I will consult the doctor in advance or tell the doctor truthfully afterwards.

I agree with the ethics committee or its representative to access my clinical research data.

I will receive a signed and dated copy of the informed consent form.

Finally, I decided to agree to participate in this clinical study and promise to follow the doctor's advice as much as possible.

Participant signature： _____ **Date:** __ __ __ __ __ __ __ __

Legal representative： _____ **Date:** __ __ __ __ __ __ __ __

Relationship with participant： _____

Phone number： _____

I confirm that I have explained the details of this clinical study to the patient, including its rights, possible benefits and risks, and gave him a copy of the signed informed consent form.

Doctor signature： _____ **Date:** __ __ __ __ __ __ __ __

Phone number： _____