Appendix I

Informed Consent Form

Study name：A Comparison of Laparoscopic With Open Distal Gastrectomy in Advanced Gastric Cancer After Neoadjuvant Chemotherapy

Protocol version：2.0, 2015 February 26

Informed consent form version：2.0, 2015 February 26

Research institute：Peking University Cancer Hospital

Patient name：　　Patient initials：

Patient address：

Patient phone number：

We invite you to participate in a clinical trial. This informed consent form provides you with some information to help you decide whether to participate in this clinical trial. Please read the following carefully, if you have unclear questions or terminology, please feel free to discuss with the reception physician.

Your participation in this study is entirely voluntary. The current study has been reviewed and approved by the Beijing Cancer Hospital Ethics Committee.

1. Research background

The purpose of this study was to provide a thorough evaluation of the safety and efficacy of laparoscopic radical gastrectomy for gastric cancer patients with neoadjuvant chemotherapy through a prospective, randomized, controlled, open-label, single-center phase II clinical study.

2. Research process:

You and your family will be informed the treatment results of this study. All data and information are confidential to people outside the study and will be used only for the purpose of this study.

Through initial abdominal/pelvic enhanced CT scan, endoscopy, etc., patients diagnosed with gastric cancer, with no clear abdominal implants, and judged feasible for radical resection, will be enrolled in the study after signing the informed consent form. Three-weeks after the neoadjuvant

chemotherapy, vital signs examinations, physical examinations, laboratory tests, 12-lead electrocardiograms in a calm state, respiratory function tests, and oncological evaluations (same categories as the screening tests) again, will be again performed to evaluate the resectability of the surgery. Resectable patients will be randomly assigned to the laparoscopic-assisted distal gastrectomy or open gastric radical gastrectomy groups. Follow-up period begins from the end of the study treatment to 3 years after the operation. Follow-up will be conducted every 3 months within the first 3 years and every 6 years in the last year. At the end of the follow-up period, statistical analysis will be performed on the patient data to obtain the final conclusion of the study. In addition, you will need to fill in the quality of life questionnaire so that we can understand your quality of life in a timely manner.

3. Risk and discomfort of participating in the study:

The risk of this project is mainly focused on adverse events as follows:

The complications associated with laparoscopic exploration include: laparoscopic surgery related risk, such as hypercapnia, hypoxemia, and bowel injury during the exploration. However, according to the previous experience of our department, the probability of bowel injury is extremely low, and can be found and dealt with accordingly in the exploration process.

Perioperative chemotherapy related adverse events: bone marrow suppression, gastrointestinal reactions, liver and kidney dysfunction, malnutrition, severe allergic reactions, peripheral neuritis,etc. MAGIC and other studies have confirmed that neoadjuvant chemotherapy did not cause additional serious side effects compared to surgery alone.

In addition, patients may experience anesthesia and surgical related discomfort including wound pain, postoperative fever, gastrointestinal discomfort after abdominal surgery including abdominal distension, abdominal pain, acid reflux, nausea, etc. A small number of patients may experience postoperative complications of radical gastrectomy including anastomotic leakage and bleeding. Most patients' condition will be relieved after conservative treatment. A very small number of patients have the possibility of worsening disease, loss of surgical opportunities, and loss of opportunities for radical cure.

4. Benefits of participating in the study:

If you agree to participate in this study, you may or may not have direct medical benefits. Patients in this study will receive a standardized diagnosis and treatment of gastric cancer. Through diagnostic laparoscopic exploration, occult peritoneal metastases will be excluded, which avoids the lack of treatment or over-treatment due to inaccurate staging to the greatest extent. Some patients may benefit from a comprehensive treatment model with perioperative chemotherapy, which increases surgical radicalness, decreases local recurrence possibility, and improves overall survival.

5. Alternative treatment:

In addition to participating in this study, you have the following options: laparotomy, radical gastrectomy

6. Costs of participating in the study: None.

7. The right to refuse to participate in or withdraw from the study:

You may choose not to participate in this study, and have the right to withdraw without any reason at any stage of the trial. Such a decision will not affect any of your medical treatment or rights. Once you have decided to participate in this study, please sign this informed consent form. Before entering the study, the doctor will evaluate your eligibility of participation.

If you choose to participate in this study, we hope you will continue to complete the entire research process.

8. Privacy and confidentiality issues:

During the research period, your personal data such as your name, gender, etc. will be replaced with a code or number and strictly confidential. Only the relevant doctors will know your information and your privacy will be well protected. The results of the study may be published in academic journals but will not reveal any of your personal data.

If you agree to participate in this study, all your medical data will be screened by relevant personnel of the organization that initiated the study, relevant authorities, or an independent ethics committee, to check the appropriateness of the study's implementation. If you sign this informed consent form, it means that you agree to receive the above persons' review.

9. Medical cost reduction

Due to the need of this trial, laparoscopic exploration is required before the laparoscopic or open gastrectomy, and the use of an ultrasonic scalpel is required for the purpose of research treatment. Therefore, the current study provides partial cost reduction for participating patients.

Item	Cost (Yuan)	Frequency	Total cost（Yuan）
ultrasonic scalpel	600	1	1,600
Laparoscopic surgery	1,000	1	

How to get help in the study:

You can have access to the information and research progress related to this study at any time point. If you have any questions related to this study, please feel free to contact Dr. Li Ziyi at 010-88196606.

If you need to know about the rights of participating in this study during the research process, you can contact the Ethics Committee of Beijing Cancer Hospital at 010-88196391.

Informed consent form—Signature page

If you fully understand the content of this research project and agree to participate in the study, you will need to sign this informed consent, in two copies, to be retained by the researcher and by you.

Research topic：

Signatory：

Declaration of Consent：

1、 I have confirmed that I have read and understood the informed consent of this study, that the problems and solutions which may arise during the course of the study have been explained to me, and that I have had the opportunity to raise my own questions.

2、 I have known that participation in the study is entirely voluntarily and refusing to participate will not jeopardize any of my interests.

3、 I have learned that the physicians involved in this study, the hospital manager of this study, and the Ethics Committee have the right to review the research records and case data, and I agree that these people will have access to my research records and understand that the above information will be treated confidentially.

4、 I agree to participate in this study.

Full name of patient name： Date:

Full name of the legal representative： Date:

Completed by the reception physician:

The researcher statement: I confirm that the patient has been explained and discussed about the nature, purpose, requirements and possible risks of the study, as well as other alternative treatment options, and that a copy of the subject's information has been given to the patient for preservation.

Full name of the researcher： Date: