

Informed Consent Form

Study Title: Establishment and Application of an Evaluation System for Precision Excision of Bowel Endometriosis

Project alias: Efficacy and Safety of Intra-operative Dual Laparoscopy and Neo-rectoscopy (IDLnR) versus Conventional Laparoscopic Surgery (CL) for Bowel Endometriosis: A Multicenter, Open-Label, Randomized Controlled Trial (LUMEN-01)

Principal Investigator: Xiaofang Yi

Research Institution: Obstetrics and Gynecology Hospital of Fudan University

You are invited to participate voluntarily in this clinical research study. Before you agree to take part in this study, please read the following information carefully and ask any questions you may have to fully understand what your participation will involve. We will also be available to answer any questions you may have at any time throughout the study period.

Study Introduction

Endometriosis seriously impairs fertility and quality of life in women of reproductive age, with a prevalence of approximately 10% – 15%. It commonly involves the ovaries, peritoneum, deep pelvic tissues, and even the intestines. Bowel endometriosis (BE) is one of the most common subtypes of deep infiltrating endometriosis and is associated with the most severe symptoms. It mainly affects the rectum, sigmoid colon, cecum, and other intestinal segments. In addition to dysmenorrhea, patients with bowel endometriosis frequently experience anal tenesmus, menstrual diarrhea or constipation, abdominal distension, rectal urgency, and even hematochezia, which substantially compromise quality of life.

Laparoscopic surgery is currently the primary treatment for bowel endometriosis. At present, high- quality clinical evidence and unified consensus regarding the assessment of intestinal lesion infiltration depth and optimal complete resection are still lacking. There is an urgent need for multicenter randomized controlled trials (RCTs) to investigate precise lesion localization, effective surgical resection, and intestinal functional prognosis in the management of bowel endometriosis.

This study aims to compare the improvement of intestinal function at 6 months postoperatively between the dual- endoscopy group (Intra-operative Dual

Laparoscopy and Neo-rectoscopy (IDLnR) and the conventional laparoscopy group (CL) in patients with bowel endometriosis.

This study has been approved by the Ethics Committee of Obstetrics and Gynecology Hospital of Fudan University as well as the ethics committees of relevant multicenter collaborating hospitals. The study is led by Dr. Xiaofang Yi from the General Gynecology Department of Obstetrics and Gynecology Hospital of Fudan University, and will be conducted in collaboration with principal investigators from all participating multicenter centers.

Study Methods

Premenopausal female patients aged 18–55 years diagnosed with bowel endometriosis (BE) and with a preoperative Low Anterior Resection Syndrome (LARS) score > 20 will be enrolled. Eligible participants will be randomized at a 1:1 ratio into the conventional laparoscopy group (control group) and the novel combined enteroscopy–laparoscopy group (experimental group).

Control Group: Conventional laparoscopy (CL) is adopted for localization, examination, and resection of bowel lesions, and surgery for bowel endometriosis is completed laparoscopically.

Experimental Group: The novel combined enteroscopy and laparoscopy technique (IDLnR) is used for localization, examination, and resection of bowel lesions, and surgery for bowel endometriosis is performed under laparoscopy.

Surgical intervention shall be performed within 0–3 days after randomization. Both surgical procedures will be strictly implemented in accordance with the specifications stated in the General Guidelines for Technical Practice of Laparoscopic Surgery issued by the Laparoscopic and Endoscopic Surgery Group, *Chinese Society of Surgery*, *Chinese Medical Association*, and the *Chinese Guidelines for Bowel Preparation Related to Gastrointestinal Endoscopy Diagnosis and Treatment* issued by the Chinese Society of Digestive Endoscopy, Chinese Medical Association.

Both groups of patients will receive standardized postoperative nursing care, including:

1. Nutritional status monitoring and pain management;
2. Assessment of surgical incisions and infection status;
3. Rehabilitation program: encouragement of early ambulation, progressive dietary adjustment, etc.;
4. Hospital discharge will be arranged 2 to 7 days after surgery according to the individual recovery condition of each patient.

Regardless of which group you are assigned to, you will be required to attend regular follow-up visits during and after the treatment period.

Follow-up contents include clinical evaluation, tumor marker detection, ultrasonography, etc. When necessary, other imaging examinations such as pelvic magnetic resonance imaging (MRI) and enteroscopy can be adopted as individualized follow-up options.

Follow-up schedule: In addition to completing standardized questionnaires regarding quality of life and intestinal function under medical guidance at baseline (before treatment) and at 1, 3, 6, and 12 months after surgery, all other treatment items, follow-up contents, and related expenses will be the same as those for patients not participating in this clinical study.

Note: The questionnaire battery includes the Low Anterior Resection Syndrome (LARS) scale, CRADI-8 scale, Wexner Constipation Scale, Gastrointestinal Quality of Life Index (GIQLI), Endometriosis Health Profile-30 (EHP-30), and Visual Analogue Scale (VAS).

Potential Benefits of Participating in This Study

Regardless of which group you are assigned to, your intestinal-related surgical treatment plan will not be affected. You will have the opportunity to consult doctors for questions about your condition during the study, as well as priority access to follow-up outpatient appointments (additional registration slots). In addition, your participation may bring benefits to other patients with the same condition in the future.

Potential Risks of Participating in This Study

If you are randomly assigned to the control group, the surgical risks are inherent to the disease itself and no additional clinical operation risks will be added. If you are randomly assigned to the experimental group, the "intraoperative novel enteroscopy-related operations" will not incur additional charges, and any potential injury risks (with zero reported cases to date) will be fully responsible by the Multidisciplinary Team (MDT) surgical team until the risks are resolved. All patients will be closely monitored for changes in intestinal function during the treatment period; please communicate with your attending doctor in a timely manner, and follow-up will be conducted until the disease outcome is confirmed.

Privacy Statement

If you agree to participate in this study, all information regarding your participation and personal data collected during the research will be kept strictly confidential. All data related to your medical course and clinical findings will be recorded in an anonymous manner. Anonymity means you will be identified only by a unique code assigned by your attending physician.

The Principal Investigator and all research staff are obligated to maintain the confidentiality of your personal information. To ensure compliance with research regulations, authorized representatives of regulatory authorities or the Ethics Committee may inspect the original medical records at the research center when necessary, including surgical reports, pathological reports, and other relevant documents.

With your understanding and cooperation, the results of this study may be published in medical journals. All research records will be protected in accordance with legal requirements. Personal identifiable information of study participants will be strictly safeguarded and will not be disclosed unless required by law. All statistical analyses and academic publications will be presented only in an anonymous format.

We guarantee that all relevant personnel shall keep the obtained information strictly

confidential. You have the right to raise objections to any reports generated during the study process. You also have the right to obtain relevant information about your medical condition and request the correction of any inaccurate information.

Compensation for Participation

All clinical procedures performed in this study comply with standard clinical diagnosis and treatment specifications. The study will not cover any fees for examinations specified in the research protocol, nor will it provide transportation allowances, work-loss compensation, or any other remuneration or subsidies to participants. Your participation in this study is entirely voluntary, and all relevant expenses shall be borne by yourself. This will not affect your standard medical treatment entitlements and legitimate rights and interests.

Indemnity

Any research-related injury or illness caused by participation in this study will be compensated in accordance with relevant laws and regulations of China. The study physician may terminate your continued participation in this study if you require additional unrelated treatment, fail to comply with the research schedule, sustain a research-related injury, or for any other reasonable clinical reason.

Rights and Obligations

Your participation in this study is completely voluntary. You may refuse to take part, or you may withdraw from the study at any time without giving any reason, even after enrollment. This will not bring any adverse consequences to you, nor will your decision affect your medical care in any way. Further treatment will be provided for you in accordance with standard clinical practice guidelines.

As a study participant, you shall undertake the following obligations: To truthfully provide your medical history and current physical condition; To inform the study physician of any discomfort experienced during the study period; Not to take any

restricted medications or foods; To inform the study physician if you have recently participated in or are currently involved in any other clinical research.

During the study, you may inquire about relevant research information at any time. Should any problems arise or if you need consultation, you may contact the attending physician, Dr. Kaikai Chang, at the phone number: +86 15221693873.

I, as a patient, have fully understood the purpose, methods, potential therapeutic benefits, and possible adverse reactions of this study. I voluntarily agree to participate in this research and pledge to cooperate fully with the medical staff.

Patient Signature: _____ Date: ____ / ____ / ____

Physician Signature: _____ Date: ____ / ____ / ____