Title： A Clinical Study on the Feasibility and Safety of Abdominal Endoscopic Single-port Surgery System to Assist Gynecological Day Surgery

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Informed Consent Form • Notice Page

Dear madam

We will invite you to participate in a clinical trial study of “a clinical study on the feasibility and safety of abdominal endoscopic single-port surgery system to assist gynecological day surgery”.

Before you decide whether to participate in this study, please read the following content as carefully as possible. It can help you understand the content of this study, why to conduct this study, and the benefits, risks and discomfort this study may bring to you.The research plan has been reviewed by the medical ethics committee of the Second Affiliated Hospital of Wenzhou Medical University and the Yuying children's Hospital of Wenzhou Medical University. It complies with the relevant laws and regulations of China and the declaration of Helsinki and other ethical principles to protect the rights and interests of subjects.

Research Introduction

1. Research Background

Robotic single-port laparoscopy is a new minimally invasive surgery method. Compared with traditional laparoscopy, it has 3D visual effect, flexible micro-joint, eliminating tremor of the hand and other technical advantages, which provides a good guarantee for the clinical development of more delicate, complex and accurate surgery.At the same time, the approximate "traceless" surgical effect is achieved, and technical limitations such as long learning curve, instrument congestion and "chopstick effect" are overcome. Although this minimally invasive approach has been shown to be applicable to gynecological benign and malignant surgery, there is no clear conclusion to prove whether robotic single-port laparoscopy is feasible and safe for gynecological day surgery.In this study, 63 patients in the Second Affiliated Hospital of Wenzhou Medical University who chose to undergo abdominal endoscopic single-port surgery system for benign gynecological diseases will be collected to analyze the feasibility and safety of abdominal endoscopic single-port surgery system to assist gynecological day surgery.

2. Research Objective

To evaluate the feasibility and safety of using a domestically produced single-port laparoscopic surgical system(SR-ENS-600) for gynecological day surgery, and to provide reference for doctors and patients in the choice of surgical methods.

3. What will I need to do if I take part in the research?

1. Your basic information, including age, BMI, and underlying diseases, will be collected. Information related to this operation, including surgery-related diseases, lesion size, lesion number, operation time, intraoperative blood loss, and postoperative pain, will be collected;

2. On discharge day, you will be required to cooperate with the researcher to complete vital signs monitoring, gynecological examination, laboratory examination, assessment of anal exhaust time, autonomous urination time, complete 6 safety evaluations, discharge score after anesthesia, and postoperative rehabilitation evaluation;

3. You will be expected to cooperate with the anesthesiologist to complete the postoperative follow-up by phone within 4 hours after discharge, including post-discharge consciousness/mental state, dizziness, sore throat, nausea/vomiting, hoarseness, limb muscle strength, pain, whether you stay overnight, drug use, etc., as well as post-discharge discharge score and safety evaluation;

4. You will be expected to cooperate with the nurse to complete the postoperative follow-up by telephone within 24 hours after discharge, including postoperative complications, drug combination, safety evaluation and postoperative rehabilitation evaluation;

5. You will be expected to complete the postoperative follow-up in the outpatient department of our hospital 30 days after discharge, which includes vital signs monitoring, gynecological examination, laboratory and imaging examination, postoperative complications, drug combination, safety evaluation, postoperative rehabilitation evaluation, quality and safety evaluation of 13 daytime operations, and scar satisfaction evaluation;

6. Your data will be accessed by researchers, but we will ensure that your privacy is not violated.

4. What are the inclusion and exclusion conditions?

- **Inclusion criteria**

1. Women aged 18 to 75 years old, with a body mass index (BMI) of no more than 32 kg/m2;

2. Conscious, no history of mental illness, accompanied by an adult during the perioperative period;

3. Educate the subjects, who are willing to undergo day surgery, understand and accept the surgical method and anesthesia method;

4. Subjects and families understand perioperative care and are willing and able to complete

post-discharge care;

5. Elective surgery, no serious complications affecting the operation and prognosis, aCCI age adjusted comorbidity index 0 points;

6. According to the adhesion risk scoring system of European Anti-Adhesions in Gynaecology Expert Panel (ANGEL), the adhesion risk was divided into three levels: high, medium and low. Subjects with low risk (0 to 12 points) and abdominal wall scarring and pelvic cavity B-ultrasonography do not indicate obvious pelvic cavity adhesion wiil be included.

- **Exclusion criteria**

1. Moderate and high-risk patients will be excluded based on ANGEL adhesion risk scoring system;

2. Subjects with hemorrhagic rupture of ectopic pregnancy and unstable vital signs;

3. Genital tract infection or in the acute phase of systemic infection;

4. Subjects on long-term anticoagulant therapy or with coagulation dysfunction;

5. Subjects have severe heart and lung disease, liver and kidney dysfunction, and cannot tolerate anesthesia;

6. A history of abdominal or diaphragmatic hernia, abnormal umbilical cord development, or umbilical surgery;

7. Not willing to undergo endoscopic surgery;

8. Participated in other drug and device clinical trials within 3 months before surgery.

5. If you participate in this study, what benefits will you get?

You may get a more accurate diagnosis by participating in this study, and you may not benefit directly. The information gained from this study may be helpful to others in the future.

6. What are the risks for me to participate in the research?

Possible intraoperative risks: heavier adhesion, more bleeding, or laparotomy; Carbon dioxide emia, air embolism, subcutaneous, retroperitoneal emphysema, hematoma; Other unpredictable accidents and complications may occur. Postoperative risk: intestinal adhesion, intestinal obstruction, venous thrombosis of lower extremity, pulmonary embolism;

Postoperative bleeding requires a second operation; Incision dehiscence, incision infection, incisional hernia; Shoulder pain; Unpredictable accidents and complications may occur.

7. Will participating in this study increase my medical expenses?

In this study, preoperative and postoperative examination and detection are required for normal clinical diagnosis and treatment, and the cost shall be borne by the subjects. The cost of the surgical robot involved in this study shall be borne by the company, and no additional cost of other tests shall be involved in this study, so this study will not increase your financial burden.

8. What will be the compensation for participating in this study?

If you participate in this study, you will receive 1000 yuan of transportation subsidy and nutrition subsidy, which will be paid after the visit is completed.

9. Damages

The sponsor has purchased clinical trial liability insurance for this study. If you suffer any injury related to this study, our research group will compensate you in accordance with relevant national laws and regulations.

10. Is personal information confidential?

If you decide to participate in this study, your personal information and related materials during the trial and your participation in the trial are confidential.All test results (including personal data, test documents, etc.) appearing in the original medical records will be completely confidential within the scope of the law, and only your initials and numbers assigned when you participate in the test will appear. If necessary, only your initials and numbers will appear in relevant research summaries, articles, and public publications.

When necessary, the drug regulatory department, the ethics committee or the project funding department can consult the data of the subjects participating in the study according to the regulations. However, without permission, they will not use the information of the subjects participating in the study for other purposes or disclose it to other groups.

11. How can I get more information?

You can ask any question about this experimental study at any time. You can consult Dr. Yang Xingyu at 17398054822. (mobile number).

If there is any important new information during the trial that may affect your

willingness to continue participating in the study, your doctor will notify you in time.

12. Do I have to take part in this research or can I quit halfway?

It is entirely up to you to participate in this study. You may refuse to participate in this study. You have the right to withdraw from the study at any time during the study. If you refuse participate in or withdraw, your benefits will not be affected, nor will you be discriminated against or retaliated for it. If you choose to participate in this study, we hope you can insist on completing the whole trial process.

Your doctor or researcher may suspend your participation in this trial at any time for the best interests of you.

13. Is there any other treatment currently available?

If you do not participate in this study, you may choose other treatment options. Please consult the investigator or your doctor for specific treatment options.

14. What should we do now?

Whether to participate in this pilot study is up to you. You can discuss with your family or friends before making a decision.

Before you make the decision to participate in the trial, please ask your doctor for relevant questions as far as possible until you fully understand the trial.

15. Ethics committee

If you have any dissatisfaction in the study, please contact the medical ethics committee of the Yuying children's Hospital Affiliated to Wenzhou Medical University, the Second Affiliated Hospital of Wenzhou Medical University.

Ethics Committee Office: Longwan District Ethics Committee Office of Yuying children's Hospital Affiliated to Wenzhou Medical University, the Second Affiliated Hospital of Wenzhou Medical University.

Contact: Teacher Chen Tel.: 0577-85676879

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

Please keep this information.

Informed Consent Form • Consent Signature Page

Declaration of consent

1. I have read this informed consent form, and the relevant person in charge of the project has explained the purpose, content, risks and benefits of this test to me in detail.
2. I have discussed and asked relevant questions about this study, and the answers to these questions are satisfactory to me.
3. I have enough time to make a decision.
4. I voluntarily agree to participate in the clinical research described in this article.
5. If I withdraw due to the reason of this product, I will inform the doctor of the change of my condition in time.
6. 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.
7. I agree with the representatives of the drug regulatory department, the ethics committee or the project funding department to consult my research materials.
8. I will obtain a signed and dated copy of the informed consent form.

Finally, I decided to agree to participate in this pilot study and promised to follow the doctor's advice.

Signature of the subject: Date:

Contact number of the subject:

Signature of legal representative: Date:

Relationship with the subject: legal representative Tel.:

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

Signature of doctor: Date:

Contact information of study doctor:

(This page is a necessary part of the subject's informed consent. Each “subject's informed consent” must be signed and dated by the subject or legal representative and the research doctor before it is valid.)