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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Study Protocol and Statistical Analysis Plan

1. Research topics

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

2. Research purpose

Evaluate the feasibility and safety of using a domestically produced single-port laparoscopic surgical system(SR-ENS-600) for gynecological day surgery, providing reference for doctors and patients in the selection of surgical methods.

3. Research background

For female ovarian cyst, ovarian endometriosis cyst, ovarian germ cell tumor, uterine fibroids and precancerous lesions and other diseases, laparoscopic surgery is the main means of treatment.Although gynecological day surgery with rapid admission has been gradually carried out in medical institutions, in the latest recommended List of day surgery issued by the National Health Commission (2022 edition), gynecological laparoscopic surgery only includes laparoscopic resection of damaged ovaries, which cannot meet the diversified surgical needs of women. Therefore, it is urgent to expand gynecological laparoscopic surgery under day medical treatment.

With the development of science and technology and laparoscopic technology, robotic single-port laparoscopic came into being.Through a single incision, it can achieve approximately "traceless" surgical effect, reduce surgical trauma and shorten postoperative recovery time, which is an important technical way to achieve day surgery. However, in the face of international export restrictions on Da Vinci® SP single-port robots and not yet approved in the field of gynecology, we urgently need to replace single-port robots with domestic production, and even realize the corner overtaking of Chinese technology.

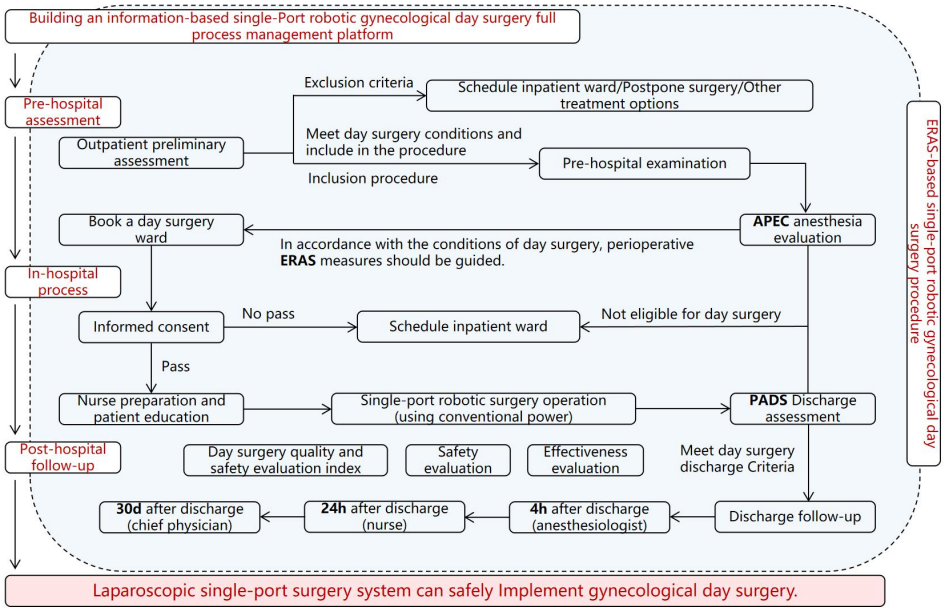
4. Research contents

In this study, the feasibility evaluation is divided into main evaluation indicators (success rate of daytime surgery) and secondary evaluation indicators (operation time, blood loss evaluation, surgeon satisfaction questionnaire, first postoperative anal exhaust time, first spontaneous urination time, pain score, length of hospital stay, postoperative rehabilitation score, abdominal incision healing, scar satisfaction, etc.).The safety evaluation of 6 objectively quantifiable safety evaluations and 13 quality safety evaluations of daytime surgery will be selected. We will conduct a prospective, single-center, single-arm clinical study to collect relevant information of patients who received intra-abdominal endoscopic single-port surgery

system to assist gynecological day surgery, and evaluate the feasibility of intra-abdominal endoscopic single-port surgery system for gynecological day surgery and the main factors affecting surgical safety through statistical analysis.

5. Research methods and technical routes

In this study, a prospective study is used to select patients who will undergo intra-abdominal endoscopic single-port surgery system for benign gynecological diseases from February 2025 to December 2026 in the Second Affiliated Hospital of Wenzhou Medical University, including hysterectomy, myomectomy, ovarian cyst removal and adnexectomy. By collecting patient baseline data (including age, BMI, underlying disease, surgery-related disease, lesion size, number of lesions), effectiveness assessment (the main evaluation indicator is the success rate of day surgery and secondary evaluation indicators included operation time, blood loss evaluation, surgeon satisfaction questionnaire, first postoperative anal exhaust time, first spontaneous urination time, pain score, hospital stay, postoperative rehabilitation score, abdominal incision healing, scar satisfaction, etc.), 6 safety evaluations(including intraoperative vital signs, intraoperative complication rate, incidence of postoperative resurgery, incidence of postoperative complications, adverse events and serious adverse events), 13 quality and safety evaluation indicators of day surgery(including the proportion of tertiary and tertiary operations, preoperative evaluation rate of anesthesia, delayed discharge rate, incidence of surgical complications, unplanned re-visit rate within 30 days after discharge, unplanned re-hospitalization rate within 30 days after discharge, unplanned re-operation rate, surgical wound infection rate, surgical site error rate, bed fall rate, fall rate, medication error rate, mortality rate).



6. The name and address of the sponsor, the site where the trial was conducted, and the name, qualification, and address of the investigator

Sponsor: the Second Affiliated Hospital of Wenzhou Medical University (Yuying children's Hospital of Wenzhou Medical University)

Address: 109 Xueyuan West Road, Lucheng District, Wenzhou, Zhejiang Province

Name of researcher: Duanping

Researcher qualifications: chief physician, Professor, doctoral supervisor

7. Type of trial design, randomization grouping method and level of blinding

Prospective study, real world study, no randomization, no blindness.

8. The inclusion criteria, exclusion criteria, the steps of selecting subjects, and the method of assigning subjects

- **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.

Calculating the number of cases need to achieve the intended purpose of the trial according to the statistical principle.

Select the step and assignment method： Appropriate patients are selected by including exclusion criteria, and after full informed consent, patients and physicians jointly select definite surgical methods.

9. The number of cases required to achieve the intended purpose of the trial

Estimation of sample size：In this study, the number of trial cases is inferred based on the method of calculating the sample size of a single group of target values, and the success rate of daytime surgery is the main outcome index. Based on the joint research and discussion of clinical trial institutions, principal investigators and statistical analysts.

According to the formula：

$$n = \frac{\left[Z_{1-\alpha/2}\sqrt{P_0(1-P_0)} + Z_{1-\beta}\sqrt{P_T(1-P_T)}\right]^2}{(P_T - P_0)^2}$$

In the formula, n is the sample size, Z1- α /2 and Z1- β are the quantiles of standard normal distribution, PT is the expected surgical success rate, and P0 is the target value.

According to clinical experience and relevant references, the target value of this study P0 is 90% and the expected success rate of day surgery PT is 99% .The number of subjects is at least 56 with a confidence of 80% (1- β) and a test level of 0.025 (unilateral). Considering that the shedding rate of subjects during the trial is about 10%, 63 cases are planned to be enrolled in this study.

10. Study risks and risk disposal plans

1) If adverse events or serious adverse events occur in patients, the treatment plan is detailed below.

2) Patients are lost to follow-up due to various reasons and the preset scheme is analyzed according to the actual surgical methods of patients.

3) 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. Preset plan, the corresponding medical treatment is provided by the doctor of the diagnosis and treatment team, and the transfer to open surgery is not included in the data analysis.

4) 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. Preset plan, regular postoperative outpatient follow-up, pay attention to patients' incision and other related prognosis outcomes. If there are postoperative complications, the doctor of the diagnosis and treatment team will provide corresponding medical treatment.

11. Criteria for discontinuing clinical trials and provisions for ending clinical trials

Criteria for patient termination of clinical trials: 1) Patients from admission to observation 1 month after surgery; 2）Patients lost to follow-up due to death, accidents and other reasons; 3）Patients occur serious adverse events; 4) Patients requested that the trial be terminated.

End of clinical trial：The prospective cohort is currently starting to count up to 63 patients, with the last person reaching the observational endpoint or discontinuing the trial for other reasons.

12. Recording requirements for adverse events and reporting methods, treatment measures, follow-up methods, time and outcome of serious adverse events

Definition of serious adverse event (SAE): refers to the death, life-threatening, permanent or serious disability or loss of function of the subject after receiving the investigational drug, as well as congenital anomalies or birth defects and other adverse medical events.In the event of a serious adverse event, investigators should report it to our Medical Ethics Committee within 24 hours of learning about it.

Treatment measures: subjects with SAE will receive clinical treatment in time and be followed up until their condition improve or they die.

13. Statistical analysis method

Single group target value test, description analysis, Pearson correlation coefficient description, Spearman rank correlation coefficient test, etc.

14. Provisions on data management and data traceability

This research group is responsible for the data management of this study to ensure the authenticity, integrity, privacy and traceability. The project leader or other authorized

researchers fill in the information in the CRF form, and only researchers with medical qualifications can fill in the original clinical evaluation / safety data. After the original data is entered, any modifications made by the project leader or other authorized researchers on the CRF form will be recorded. Any modification of approved data will make the name of the modified researcher or other authorized researcher, the date of modification and the reason for modification (if the change is not significant).

15. Quality control of test

Researchers will adopt standard operating procedures to ensure the quality control of clinical trials and the implementation of quality assurance system. All observations and findings in the clinical trial will be verified to ensure the reliability of the data and ensure that all conclusions in the clinical trial are derived from the original data. Quality control is adopted at each stage of data processing to ensure that all data are reliable and processed correctly.

16. Ethical requirements;

1) Before the clinical trial, the trial plan needs to be reviewed by the ethics committee. The review result is consent, and the approval document can be signed before implementation.

2) During the trial, the WMA declaration of Helsinki (2013), CIOMS International Ethical Guidelines for human biomedical Research (2016) and National Health and Family Planning Commission of the ethical review for biomedical research involving humans beings (2016) will be followed.

3) During the trial, any modification of the clinical research protocol, informed consent, recruitment materials, etc. must be reviewed and approved by the ethics committee before implementation.

4) Before each subject is selected for this study, the researcher must introduce to the subject in detail the purpose of this study, the test process and duration, the inspection operation, the expected possible benefits and risks of the subject, the money and time that may be spent. In addition, the researcher needs to inform the subjects that participating in this trial is entirely voluntary, and has the right to withdraw from the trial at any stage of the trial without discrimination and retaliation, and their medical treatment and rights will not be affected.

5) After the investigator has fully and in detail explained the situation of the test, the subject or his legal representative (for the incapacitated subject) should sign and date the informed consent form. The investigator performing the informed consent process should also sign the name and date on the informed consent form. The informed consent form is in duplicate, which should be kept by the subject and the investigator respectively.

17. Expected progress and completion date of clinical research

Time	Expected progress
2025.03.01～2026.3.31	Recruit patients,complete the operation and complete postoperative follow-up
2025.04.01～2025.06.30	Collect and analyze data
2026.07.01～2026.12.31	Complete project summary, appraisal, results declaration, etc

18. Follow up and medical measures after the end of the study

None.

19. Responsibilities of each party and other relevant provisions

In case of any damage related to this experimental study, the project research team will compensate according to relevant national laws and regulations.

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