Comparative Study on the Efficacy of High-Definition Electronic Amplification Endoscopy Combined with Image Enhancement Technology and Colposcopy in the Exploration of Cervical and Vaginal Pathologies

Informed Consent Form for Study Participants • Informed Consent Page

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Dear research participants:

We are conducting a research project titled "Comparative Study on the Efficacy of High-Definition Electronic Amplification Endoscopy Combined with Image Enhancement Technology and Colposcopy in the Exploration of Cervical and Vaginal Pathologies." Your condition may meet the inclusion criteria for this study, and we will invite you to participate. This research has been reviewed and approved by the Medical Research Ethics Committee of West China Second University Hospital, Sichuan University.

Before deciding whether to participate in this study, please read the following information as carefully as possible. This will help you understand the study itself, the rationale for its conduct, the procedures and duration of the study, as well as the potential benefits, risks, and discomforts associated with participation. If desired, you may also discuss the matter with your relatives or friends, or seek explanations from the investigators to assist in making an informed decision.

1、Research task source: This project is an IIT research jointly initiated by the Department of Gynecology at West China Second University Hospital of Sichuan University and the Department of Gastroenterology at West China Fourth University Hospital of Sichuan University. The research leaders at our center include Professor Wang Ping and Professor Zhou Shengtao from the Department of Gynecology at West China Second University Hospital.

2、Research Objective: This study aims to compare the diagnostic performance (accuracy, sensitivity, specificity, positive predictive value, negative predictive value, etc.) of high-definition electronic magnification endoscopy combined with image enhancement technology versus colposcopy in screening cervical and vaginal lesions. The objective is to clarify the advantages of high-definition magnification electronic endoscopy and verify its potential to replace colposcopy as a first-line diagnostic tool. This examination can reduce unnecessary biopsies and cervical canal curettage in study participants due to the uncertainty associated with colposcopy and the difficulty in exposing the cervical canal, thereby alleviating discomfort and associated medical

costs caused by the procedure.

3、Study period: March 28,2026 to March 28,2030

4、Study Protocol Overview: For study participants with indications for colposcopy, the examination sequence was randomly assigned according to a randomized controlled table. The procedure involved sequential colposcopy/high-definition electronic magnification endoscopy combined with image enhancement technology. After performing saline solution tests, acetic acid tests, and iodine tests, image acquisition was conducted for each enrolled participant. Submicroscopic image features were recorded, and lesion grades were preliminarily diagnosed as low-grade or high-grade. Colposcopy physicians collected biopsy specimens from suspicious lesions for pathological examination. If biopsy was unnecessary, follow-up re-examination after 6-12 months was optional, with subsequent decisions regarding colposcopy and biopsy based on follow-up results. Comparative analysis of image features between the two examinations was performed. Pathologists conducted microscopic examination of biopsy specimens and issued pathological results (pathologists were unaware of the preliminary diagnostic conclusions from both examinations). The accuracy of the two examination methods was validated using biopsy results and follow-up outcomes. High-definition electronic magnification endoscopy combined with image enhancement technology is primarily used for gastrointestinal disease diagnosis and treatment. In this study, it was employed beyond its standard indications but exclusively for image acquisition without skin contact, thus avoiding discomfort or adverse effects beyond those associated with routine colposcopy. The entire study complied with the Helsinki Declaration and the "Ethical Review Guidelines for Life Science and Medical Research Involving Human Subjects" and other relevant regulations.

5. Study plan: Number of enrolled participants and inclusion/exclusion criteria: This study will be conducted at (2) research centers, with a total planned enrollment of (270) participants, of which 135 will be recruited at this center.

5.1 Inclusion criteria:

① Age 18-65 years, with indications for colposcopy: human papillomavirus (HPV) 16/18 positive; HPV non-16/18 positive, cervical liquid-based cytology (LCT/TCT) ≥ atypical squamous cell sign (ASCUS) with unclear significance; HPV negative, LCT ≥ low-grade squamous intraepithelial lesion (LSIL); persistent HPV infection ≥ 1 year.

② Voluntary signing of the informed consent form.

5.2 Exclusion criteria:

① Pregnant or lactating women.

② Acute genital tract infection, severe coagulation disorders.

③ History of radiotherapy for malignant tumors or severe mental disorders.

④Minor female

5.3 Exit criteria:

①Study participants requested to withdraw.

② Occurrence of severe adverse events (e.g., major bleeding, allergic reactions).

5.4 Study Group Allocation and Methods: All 270 study participants underwent both traditional colposcopy and endoscopy examinations. Sequential randomization was performed using a simple randomization method at a 1:1 ratio (Sequential Group A: Traditional colposcopy was used first for observation and image acquisition, followed by endoscopy; Sequential Group B: Endoscopy was used first, followed by colposcopy).

6. During the study period, your required actions are as follows: After fully understanding the study methodology, you will voluntarily sign an informed consent form. Depending on the group assignment, you will undergo examination using either traditional colposcopy or endoscopy. Based on the findings under the scope and clinical needs, cervical or vaginal wall biopsies may be performed (approximately 2-4 mm/2-4 tissue samples will be collected depending on lesion size for submission). If both traditional colposcopy and endoscopic examinations show no abnormalities, you may voluntarily opt for biopsy after receiving comprehensive informed consent. Results from both endoscopic examinations will be communicated to you. Participants opting for biopsy will submit 2-4 mm/2-4 tissue samples as required. If you choose not to undergo biopsy, follow-up HPV and TCT tests will be conducted at 6-12 months. Your cooperation is required for the entire procedure, which will take approximately 10 minutes. Approximately 24 hours after completing the examinations, we may follow up to assess your pain levels and potential complications.

7. Potential risks and benefits of participating in this study:

7.1 Research Risks and Mitigation: This study is a prospective, multicenter clinical trial that may involve information security risks. We will make every effort to protect the information you provide from disclosure. Some questions you may be asked during the study may cause discomfort, and you may opt to decline responses to such questions. Participation in this study will not incur additional time or financial costs. During the procedure, you may experience mild pain, which is within the

tolerable range compared to conventional colposcopy. The examination process, including medications, gauze, biopsy forceps, and other equipment used, is identical to that of traditional colposcopy. The only difference lies in the imaging tools employed. No additional biopsy specimens will be collected due to your participation. You may rest at any time during the procedure. In the event of severe bleeding, infection, or allergic reactions caused by this study, we will provide immediate and comprehensive medical intervention. You may withdraw from the study at any time during the research period.

7.2 Research Benefits: This study does not affect the diagnosis or treatment of study participants, thus no benefit modification occurs. However, your participation may provide future benefits in "more precise examination of cervical and vaginal lesions," offering valuable information for research or diagnosis and treatment of cervical and vaginal lesions using high-definition electronic magnification endoscopy.

8. Fees and Compensation: Endoscopic examinations used in this study are free of charge, and you only need to pay the standard colposcopy fee (87 CNY). Participation in this study will not increase your medical expenses. Considering the potential inconvenience caused by your participation, an additional compensation of 100 CNY will be provided. We sincerely appreciate your involvement. In the event of any study-related injuries occurring during participation, the research team will provide corresponding treatment and compensation in accordance with national regulations.

9. Alternative Treatment Options: You may choose to opt out of this study, which will not adversely affect your access to conventional treatment. Based on your current health status, conventional treatment options include: performing only traditional colposcopy, with biopsy taken if necessary according to endoscopic findings to guide subsequent management. If biopsy is not required, regular follow-up examinations are recommended. Traditional colposcopy has a long history and is performed by experienced physicians, but its imaging quality is suboptimal, resulting in poor visualization of the cervical canal, which may lead to unnecessary biopsies and endocervical curettage (ECC).

10. Principle of Voluntary Participation: Your participation in the study is entirely voluntary, and you may decline to participate. You have the right to withdraw from the study at any stage without facing discrimination or retaliation, and your treatment and rights will not be affected.

In the best interest of your participation, if additional treatments are required, you fail to adhere to the study protocol, or if study-related risks outweigh potential benefits or other factors that may compromise the study's progress, the investigators may suspend/terminate your continued participation in this study during the research process. In the event of premature termination of this study, we will promptly notify you, and your research team will provide appropriate recommendations based on your health status or the current study situation.

11. Measures for the protection/confidentiality of participant information and privacy: The study data will be stored in accordance with regulations at West China Second University Hospital of Sichuan University, and researchers, the principal investigators, and the ethics review committee may access the study materials. Any public reports related to the study findings will not disclose your personal identity unless you grant explicit permission. We will make every effort to protect the privacy and personal information of your study data within the legal framework.

12. Access to Additional Information: Prior to participating in this research project, you should acquire as comprehensive understanding as possible regarding the study details. Throughout the research process, you may obtain relevant information and updates on study progress at any time. Should you have any questions or concerns pertaining to this study, please feel free to consult the principal investigator. Researchers will promptly notify you of any significant new information that may affect your willingness to continue participation. For inquiries regarding ethical considerations and your rights, please contact the Medical Research Ethics Committee of West China Second University Hospital, Sichuan University, at telephone number: 028-88570104.

Exploration of Clinical Application Value of High-Definition Electronic Amplification Endoscopy Combined with Image Enhancement Technology in Screening for Cervical and Vaginal Pathologies: A Prospective, Multicenter, Randomized Controlled Clinical Study

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Study participant statement:

The principal investigator of this study provided detailed and accessible explanations regarding the aforementioned matters and answered all my questions. I have fully understood my rights, benefits, obligations, and risks associated with this study. After thorough consideration, I voluntarily agreed to participate in this study and actively cooperated with the investigators to complete the research.

Participant signature: Date:

Participant signature: Date:

Researcher's statement:

As a researcher, I have provided detailed explanations to study participants (or their guardians) regarding the study, including its objectives, procedures, risks and benefits, participation principles, and data confidentiality. I have allocated sufficient time for them to review the informed consent form and discuss it with others, and have addressed all questions raised. I have informed the study participants (or their guardians) that they may withdraw from the study at any time without affecting subsequent treatments.

Researcher's signature: Date:

Researcher's signature: Date:

Contact information for researchers: