Informed Consent Form

Official Title： The impact of rabeprazole-based triple therapy plus bismuth for first-line *Helicobacter pylori* eradication on the vaginal microecology change: a prospective, randomized controlled trial

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AF42 Informed Consent Form for Human Research at the Second Affiliated Hospital of Zhejiang University School of Medicine

Dear Patient, We invite you to participate in a clinical study titled "The Impact of *Helicobacter pylori* Eradication Therapy on the Female Vaginal Microbiota". Before deciding whether to participate, please carefully read the following content, which will help you understand the purpose of the study, its procedures and duration, as well as the potential benefits, risks, and inconveniences that may arise from participation. Below is an introduction to the study:

1) Research Background and Objectives

Research Background *Helicobacter pylori (H. pylori*) is closely associated with chronic gastritis, peptic ulcers, gastric cancer, and gastric MALT lymphoma, and is classified as a Group I carcinogen. Both the 6th National Consensus Conference on Helicobacter pylori in China and the Maastricht Ⅵ Consensus Conference have proposed that "*H. pylori* gastritis is an infectious disease, and *H. pylori*-infected individuals should undergo *H. pylori* eradication unless there are countervailing factors". The female vaginal microbiota is part of the human microecosystem. Imbalance of the vaginal microbiota is

characterized by abnormal vaginal flora and altered vaginal pH, which reduces the vagina's resistance to pathogenic microorganisms and predisposes to secondary infections. Currently, there are no domestic or international research reports on the impact of *H. pylori* eradication therapy on the female vaginal microbiota. Research Objectives ① Clarify the impact of Hp eradication therapy on the female vaginal microbiota; ② Analyze the safety of the research protocol.

2) **Specific Procedures and Processes**

Patients eligible for *H. pylori* eradication will be enrolled in the standard *H. pylori* quadruple therapy group. The course of *H. pylori* treatment is 14 days. Six to eight weeks after the completion of treatment, 13C-urea breath test will be performed to assess *H. pylori* eradication status. Routine leukorrhea examination and vaginal microbiota detection will be conducted before treatment, 2 weeks after treatment, and 8 weeks after treatment.

Study duration: From the date of ethical approval and completion of clinical registration. 1) Treatment Regimen - Rabeprazole: 10mg, twice a day (BID), for 14 days - Colloidal Bismuth Pectin: 200mg, twice a day (BID) - Amoxicillin: 1.0g, twice a day (BID) - Clarithromycin: 0.5g, twice a day (BID) 2)

Study Flowchart *Hp*-positive patients with chronic gastritis ↓ Exclusion criteria: - Patients who are unwilling to participate; - Postmenopausal women; - Women of childbearing age ↓ *H. pylori* quadruple eradication therapy ↓ - Before treatment, 2 weeks after treatment, 8 weeks after treatment: Routine leukorrhea examination and vaginal microbiota detection - 6-8 weeks after treatment completion: ^{13}C-urea breath test to assess *H. pylori* eradication status If you agree to participate in this study, you will receive 14-day *H. pylori* eradication therapy (detailed medication regimen as above). Routine leukorrhea examination and vaginal microbiota detection will be performed before the start of treatment, 2 weeks after treatment, and 8 weeks after treatment. A ^{13}C-urea breath test will be conducted 6-8 weeks after treatment completion. During treatment, there are risks of gastrointestinal reactions, allergies, etc. Gastrointestinal reactions such as bitter taste and nausea caused by clarithromycin are relatively common, but can be minimized through standardized medication administration. Clinical experience has shown that the vast majority of patients can tolerate and successfully complete the eradication therapy.

3) What You Need to Do If You Participate in the Study

Your treatment will be carried out in full accordance with routine clinical practice. You may withdraw from the study at any time without any penalty or loss of any benefits you are entitled to. However, if you decide to withdraw during the study, we encourage you to consult your doctor first. For safety reasons, a relevant examination may be conducted after withdrawal.

4) Potential Benefits of Participating in the Study

If you agree to participate, you may receive direct medical benefits, such as successful *H. pylori* eradication, improvement of chronic gastritis, recovery of physical and mental health, and monitoring of vaginal infections. We hope that the information obtained from your participation will benefit other patients with similar conditions in the future. However, it is also possible that you will not receive the aforementioned direct medical benefits.

5）Potential Adverse Reactions, Risks, and Risk Prevention

Measures The potential risks of participating in this study are as follows. You should discuss these risks with your research doctor or, if you wish, with your regular attending physician. The medications used in the study may cause the following adverse reactions. You may experience some, all, or none of these: - Nausea, abdominal discomfort, diarrhea, bitter taste, etc.

- Dizziness, fatigue - Impairment of liver or kidney function - Rash, esophagitis, etc. If you have any questions related to this study, please contact your attending physician. If you have any questions related to your rights and interests, or if you wish to report difficulties, dissatisfaction, or concerns encountered during the study, or provide opinions and suggestions related to the study, please contact the Hospital Ethics Committee or the Ethics Review Committee of the Second Affiliated Hospital of Zhejiang University School of Medicine. In the event of an unforeseen serious adverse event with severe consequences related to this study that meets the terms of the hospital's insured clinical research liability insurance, the hospital will assist you in claiming compensation from the insurance company.

6）Explanation of Costs

Your treatment will be carried out in full accordance with routine clinical practice. You will be responsible for the costs of medication treatment and re-examination via ^{13}C-urea breath test. The costs of routine leukorrhea examination and vaginal microbiota detection will be covered by the research team's funds.

7）Alternative Options

If you do not agree to participate in this study, we will recommend other treatment options for you, such as other anti-*H. pylori* eradication regimens composed of different antibiotics and proton pump inhibitors. For studies involving the collection of tissue samples that do not involve clinical treatment, it can be noted that if you are unwilling to participate, there are no alternative options, and this will not affect your routine clinical treatment.

8）Confidentiality of Your Personal Information

Your medical records (including research medical records and physical and chemical examination reports) will be stored in the hospital in accordance with regulations. Only researchers, the Ethics Committee, monitors, auditors, drug regulatory authorities, and other relevant personnel will be allowed to access your medical records. Personnel unrelated to the study are not entitled to access your medical records without permission. Public reports of the study results will not disclose your personal identity. We will make every effort to protect the privacy of your personal medical information within the scope permitted by law.

9）Termination of Study Participation

Participation in this study is entirely voluntary. You may refuse to participate or withdraw from the study at any time without reason during the study period. This will not affect your relationship with your doctor, nor will it affect your medical treatment or other benefits. In addition, your participation in the study may be terminated for the following reasons: 1. You fail to follow the doctor's advice. 2. You develop a serious condition that may require treatment. 3. The research doctor believes that terminating the study is in your best health and welfare interests.

10）Ethics Committee

This study has been reported to the Human Research Ethics Committee of the Second Affiliated Hospital of Zhejiang University School of Medicine, which has conducted a comprehensive review, including an assessment of risks to participants, and granted approval. For matters related to ethics and rights during the study, you can contact the Human Research Ethics Committee of the Second Affiliated Hospital of Zhejiang University School of Medicine: - Daytime phone: 0571-87783759 - Night (general duty): 13757118366 - Email address: HREC2013@126.com

I confirm that I have read and understood this informed consent form, voluntarily accept the treatment methods in this study, and agree to the use of my medical data for the publication of this study.

Signature of Participant: _____ Contact Information: _____ Date: _____

Signature of Legal Representative (if applicable): _____ Relationship with Participant: _____ Contact Information: _____ Date: _____

Witness (if applicable): _____ Contact Information: _____ Date: _____

I confirm that I have explained the details of this study to the patient, including their rights, potential benefits, and risks, and provided them with a signed copy of this informed consent form.

Signature of Researcher: _____

Contact Information (Mobile Phone): _____ Date: _____