Zhengzhou University First Affiliated Hospital Informed Consent Form-Information Disclosure Page

Study Title: Exploring Methods for Treating Hypergastrinemia in Patients with Autoimmune Gastritis: A Prospective Study

Applicant: Zhengzhou University First Affiliated Hospital Department of Gastroenterology Ward 2

CRO: None

Protocol Number: None

Protocol Version Number and Version Date: 1.0, January 30,2024

Research Institution Name: Zhengzhou University First Affiliated Hospital

Research Institution Address: No.43 Daxue Road, Zhengzhou City, Henan Province

Principal Investigator:

Contact Phone Number:

Patient Initials:

Patient Screening Number:

Patient Informed Consent Form

1、Research Background Introduction:

You will be invited to participate in a clinical study initiated by the First Affiliated Hospital of Zhengzhou University. This study aims to explore methods for treating hypergastrinemia

in patients with autoimmune atrophic gastritis and is expected to last for one year. The research project has undergone project review by the Research Department of the First Affiliated Hospital of Zhengzhou University and has been approved by the Ethics Committee of the hospital, granting permission to conduct the clinical research.

This informed consent form provides you with relevant information about this clinical study to help you decide whether to participate in this clinical study. If you agree to participate in this study, please read the following contents carefully. If you have any questions, please ask the researcher in charge of this study.

2、Research Purpose：

(1) To investigate the safety and efficacy of oral Betaine hydrochloride (BHCL) in treating hypergastrinemia in patients with autoimmune gastritis, aiming to use a convenient and feasible approach to reduce the risk of type 1 gastric neuroendocrine tumors in patients with autoimmune gastritis.

(2) To further enhance understanding of autoimmune gastritis and type 1 gastric neuroendocrine tumors.

3、Research Process and Methods：

If you agree to participate in this study, each participant will

be assigned a unique identification number, and the study will follow the principle of randomization to allocate participants into different groups. Group A participants will only take oral administration of placebo, one capsule three times a day. Group B participants will only consume oral administration of a compound digestive enzyme capsule, one capsule three times a day. Group C participants will only consume oral administration of Betaine hydrochloride (BHCL),one capsule before each meal. Blood samples will be collected before the start of the trial and three months after the trial to measure serum gastrin levels. The differences in gastrin levels before and after the trial will be compared within each group, as well as the differences in gastrin levels among the different groups after the trial.

4、Potential Benefits of the Research：

Autoimmune atrophic gastritis is characterized by immune-mediated destruction of gastric wall cells,

Leading to insufficient gastric acid secretion and compensatory hyperplasia of gastric G cells with elevated gastrin levels. Elevated gastrin levels may increase the risk of type1 gastric neuroendocrine tumors. The supplementation of acid agents may potentially induce negative feedback

regulation on gastrin secretion, thereby reducing gastrin levels and potentially decreasing the risk of type 1gastric neuroendocrine tumors in patients with autoimmune atrophic gastritis. However, it is important to note that participation in this study does not guarantee any benefits for you.

5、Research Risks and Discomforts：

When taking acid agents, some patients with gastroesophageal reflux disease (GERD) may experience more severe symptoms such as acid reflux and heartburn

6、Other Alternative Treatment Methods：

To improve symptoms of indigestion, supplementation of digestive enzyme can be considered. Additionally, supplementation of folic acid and vitamin B12 can help improve mental symptoms. It is also recommended to undergo regular gastric endoscopy to assess the risk of developingtype1gastricneuroendocrinetumors.

7、Privacy Protection： If you decide to participate in this study, your participation in the study and personal information in the research will be kept confidential. For you, all information will be confidential. Your polyp samples will be identified by study number rather you're your name.

Information that can identify your identity will not be disclosed to members outside the research team without your permission. All research members and applicants are required to keep your identity confidential. Your files will be kept in the file cabinet of the Gastrointestinal Endoscopy Center of the First Affiliated Hospital of Zhengzhou University and will only be reviewed by researchers. If necessary to ensure that the study is conducted as required, members of government regulatory agencies or ethics review committees may review your personal data at the research unit as stipulated. Confidentiality will also be promised when the results of this study are published.

8、Costs and Compensation：

While acid agents like Betaine hydrochloride（BHCL) can be consumed as dietary supplements,

There is still a risk of potential accidents and complications. During your participation in the research, if any harm related to the study occurs, you may be eligible for corresponding financial compensation. The responsibility for covering the compensation expenses lies with Professor Yao Jianning's team.

9、Free Withdrawal：

As a subject, you can understand the information and progress related to this study at any time, and voluntarily decide whether to (continue) participate or not(continue)to participate. After participating, you can choose to notify the researcher at any time to withdraw from the study, regardless of whether harm occurs or is severe. Your data after withdrawal will not be included in the study results, and your medical treatment and interests will not be affected. If continuing the study causes you serious harm, the researcher will also terminate the study.

If you have any questions about the study content, please contact us at 0371-66271117. If you have questions related to your own interests, you can contact the ethics committee through the contact information at the bottom of the informed consent form.

10、Research Outcome Sharing After Completion of Study:

If Betaine hydrochloride (BHCL) is proven to effectively decrease gastrin levels in patients with autoimmune atrophic gastritis, this method may be widely applied in clinical settings to reduce the risk of developing type 1 gastric neuroendocrine tumors in patients with AIG. It is important to conduct further research and clinical trials to validate the

effectiveness and safety of this approach before it can be widely implemented.

Zhengzhou University First Affiliated Hospital Informed Consent Form-Consent Signature Page

I have carefully read the informed consent form for the clinical trial exploring the treatment of hypergastrinemia in patients with autoimmune atrophic gastritis. I have had the opportunity to ask questions, and all my questions have been answered. I understand that participation in this trial is voluntary, and I have the option to decline participation or withdraw from the trial at any time without facing discrimination or retaliation. My medical treatment and rights will not be affected by my decision. There searchers have the right to terminate my participation in the clinical trial if I require alternative diagnosis/ treatment, fail to comply with the trial protocol, or for any other reasonable cause. I voluntarily consent to participate in this clinical trial, and I will be provided with assigned copy of the informed consent form.

Please copy: I have read and understood this clinical trial, and I voluntarily agree to participate in this clinical trial._____

_____.

Participant Name：

Participant Signature:

Participant ID Number:

Contact Telephone Number：

Date：

(When a participant lacks or has limited capacity to consent, add or replace the following:)

Guardian Name：

Guardian Signature：

Guardian ID Number：

Relationship to Participant：

Contact Telephone Number：

Date：

(When the participant or their guardian is unable to read, add or replace the following:)

Impartial Witness Name：

Impartial Witness Signature：

Impartial Witness ID Number：

Contact Telephone Number：

Date：

I have accurately informed the participant of the contents of the informed consent form and answered the participant's questions. The participant voluntarily agrees to participate in this clinical trial. I have also provided the participant with assigned copy of the informed consent form.

Research Physician Name:
Research Physician Signature:
Contact Telephone Number:
Date: