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

Study Title:	The Impact of Repeat Colonoscopy Insert Method on the Detection Rate of Adenomas in the Sigmoid Colon.
Applicant:	Zhengzhou University First Affiliated Hospital Department of Gastroenterology Ward 2
CRO	None
Protocol Number:	None
Protocol Version Number and Version Date:	1.0, November 8, 2023
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 and conducted by the Gastrointestinal Endoscopy Center of the First Affiliated Hospital of Zhengzhou University. This study aims to explore whether secondary colonoscopy can improve the detection rate of adenomas. The study will last 1 year. This study has been approved by the Scientific Research Department of the First Affiliated Hospital of Zhengzhou University and

the Ethics Committee of the First Affiliated Hospital of Zhengzhou University to conduct 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：

Colorectal cancer (CRC) is one of the most common malignant tumors worldwide. In 2020, it is estimated that there will be 19.3 million new cancer cases (CRC accounting for 10.0%) and 10 million cancer deaths (CRC accounting for 9.4%) worldwide. Its incidence ranks third among all cancers globally, and its mortality rate ranks second. It is the leading cause of incidence and mortality of digestive system tumors worldwide, posing a serious threat to people's lives and health. Studies have shown that 70%-90% of CRCs follow the "adenoma-carcinoma" sequence, that is, most colorectal cancers develop from colorectal adenomas, and it generally takes 10-15 years for adenomas to progress to cancer, providing an important time window for early diagnosis and clinical intervention of the disease. Colonoscopy is currently the most effective means of detecting colorectal adenomas, but the miss rate of adenomas is still relatively high and the adenoma detection rate is still at a low level with the current examination and observation methods. Experiences from Western countries show that in asymptomatic average risk populations over 50 years of age, ADR should be ≥25% for males and ≥20% for females, while recent studies have shown that the ADR in the Chinese population is only 14%-15%, indicating that there is still a large gap between China and developed countries in terms of adenoma detection level. Currently, the traditional colonoscopy examination in China adopts the retroflexion

observation method, that is, the colonoscope is inserted along the colonic lumen while inflating the colon and advancing the colonoscope to the cecum, and then observes the cecum, ascending colon, transverse colon, descending colon, sigmoid colon and rectum sequentially during withdrawal. During insertion, in order to ensure the cecal intubation rate, the endoscopist controls the amount of insufflation to keep the colonic lumen in a compressed state, so that the scope axis and colon axis are in the same straight line, enabling the scope to insert into the cecum more quickly and smoothly. With the traditional examination method and successful intubation of the cecum, the length of the colonoscope is about 70-80cm, while the length of the colon is about 150cm, so that only the compressed state during the process, plus the colon itself with many folds, some hidden polyps and adenomas in the folds may be missed. Some polyps and adenomas can only be found during insertion due to their special positions, suggesting that we need to further optimize the current colonoscopy examination method to improve the quality of colonoscopy. Since the sigmoid colon has more turns, it is more likely to be compressed during insertion. Therefore, we propose the method of secondary colonoscopy observation of the sigmoid colon: performing secondary colonoscopy on the sigmoid colon based on the traditional colonoscopy examination method, and observing during both insertion and withdrawal. In order to explore whether secondary colonoscopy of the sigmoid colon can further improve the adenoma detection rate to improve the quality of colonoscopy and reduce interval cancers, we conducted this study.

3、Research Process and Methods：

If you agree to participate in this study, we will assign a study number to each subject and randomize them into groups according to the randomization principle. Group A patients will only undergo colonoscopy once and will be observed during withdrawal. Group B patients will undergo

secondary colonoscopy of the sigmoid colon after the first withdrawal observation, and will be observed during both insertion and withdrawal. During colonoscopy, we will take pictures, remove polyps, and send them for pathology examination of any lesions in your colon and rectum. Your relevant information will only be used for this study.

4、Potential Benefits of the Research:

Colonoscopy is currently the most effective means of detecting polyps, adenomas and colorectal cancer in the colon and rectum. Participating in this study will help diagnose any related benign or malignant diseases in your colon and rectum, and help provide you with subsequent treatment and colorectal cancer prevention recommendations. The study data will provide useful information for related research on colorectal cancer diagnosis and treatment.

5、Research Risks and Discomforts:

Risks of colonoscopy:

(1) Various adverse reflexes during examination may cause cardiovascular accidents or respiratory cardiac arrest;

(2) Gastrointestinal bleeding, even life-threatening massive gastrointestinal bleeding;

(3) Gastrointestinal perforation causing pneumoperitoneum, subcutaneous emphysema, etc.;

(4) Combined with other diseases or organ damage may aggravate existing diseases;

(5) Repeated biopsies according to the doctor's judgement based on the condition but still cannot make a clear diagnosis;

(6) Other extremely low incidence but unpredictable accidents and complications caused by combined latent underlying diseases.

Risks of anesthesia for painless endoscopy:

(1) Abnormal reactions such as allergies and poisoning caused by the use of anesthetics and other drugs, leading to shock, serious organ dysfunction or even respiratory cardiac arrest;

(2) Various adverse reflexes during examination may cause cardiovascular accidents or respiratory cardiac arrest;

(3) Combined with other diseases or organ damage may aggravate existing diseases;

(4) Anesthesia methods during examination are determined by the anesthesiologist based on medical needs, and drugs outside the scope of medical insurance may be applied if necessary;

(5) Postoperative nausea, vomiting, somnolence, irritability, awareness during procedure, postoperative recall and other psychological symptoms;

(6) Other unpredictable accidents and complications.

In case of the above risks and accidents, doctors will take active response measures.

6、Other Alternative Treatment Methods:

When the detected lesions are not suitable for polypectomy, we will use EMR (endoscopic mucosal resection) or ESD (endoscopic submucosal dissection) to treat the lesions.

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 than 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:

Colonoscopy examination is widely carried out currently to clearly diagnose diseases and alleviate patients' discomfort. As a new diagnostic technology, it causes less pain, has high accuracy and proven high safety for patients. However, accidents and complications may still occur during the examination process. If you suffer from any harm related to the study during your participation in the research, you will be entitled to appropriate compensation according to relevant laws and regulations. You will not bear any cost for participating in this study. If your health is damaged by study procedures, the research team will be responsible for providing medical treatment and appropriate economic compensation according to relevant laws and regulations.

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:

After the publication of research conclusions, relevant results will be published in academic conferences or related journals in the form of academic reports or papers. You have the right to understand the research results, and we will also introduce the research outcomes to you through appropriate means. If this method can indeed improve the adenoma detection rate, it is hoped that it can be applied in clinical practice to improve the quality of colorectal cancer screening in China and reduce the incidence rate. Your contributions to this study will be on record and will have positive significance in improving public health in China.

Zhengzhou University First Affiliated Hospital

Informed Consent Form - Consent Signature Page

I have carefully read the informed consent document for the clinical trial titled "The Impact of Secondary Sigmoid Colonoscopy on Adenoma Detection Rate" and have had the opportunity to ask questions, which have been answered to my satisfaction. I understand that my participation in this trial is voluntary and that I may choose not to participate or to withdraw from the trial at any time without penalty or loss of benefits to which I am otherwise entitled. My medical care and legal rights will not be affected if I do not participate or I withdraw. The investigator may terminate my participation in the trial if necessary for my treatment, for administrative reasons or if required by the trial sponsor, or if other circumstances arise which warrant doing so. I freely agree to participate in this clinical trial and will receive a signed copy of this 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: _____day_____month_____year

(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: _____day_____month_____year

(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: _____day_____month_____year

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 a signed copy of the informed consent form.

Research Physician Name: _____

Research Physician Signature: _____

Contact Telephone Number: _____

Date: _____day_____month_____year