A prospective, multi-center study to characterize intestinal fibrosis in patients with Crohn's disease (CD) using MR enterography (MRE)-based artificial intelligence

NCT Number: None

-December 17, 2024-

Informed Consent Form

Project Title: A prospective, multi-center study to characterize intestinal fibrosis in patients with Crohn's disease (CD) using MR enterography (MRE)-based artificial intelligence

Informed Consent Form Version: 4.0, December 17, 2024

Principal Investigator:_____

You are invited to participate in a clinical research study. This informed consent form provides you with information to help you decide whether to participate in this study. Please read it carefully. If you have any questions, please ask the researchers responsible for this study. Your participation in this study is voluntary. This study has been reviewed and approved by the Ethics Review Committee of the research institution.

1. Purpose of the Study

This study aims to develop and validate a deep learning model (DLM) based on magnetic resonance enterography (MRE) to effectively characterize intestinal fibrosis caused by Crohn's disease (CD).

2. Study Procedures

This study is a prospective, multi-center observational clinical trial lasting 24 months, with the First Affiliated Hospital of Sun Yat-sen University as the sponsor. The study plans to recruit 234 patients with CD requiring intestinal resection due to ileal or colonic stricture from five medical centers, including 80 patients from this hospital. The five participating medical centers are: the First Affiliated Hospital of Sun Yat-sen University, the Sixth Affiliated Hospital of Sun Yat-sen University, Sir Run Run Shaw Hospital of Zhejiang University School of Medicine, Ruijin Hospital affiliated with Shanghai Jiao Tong University School of Medicine, and Jinling Hospital affiliated with Nanjing University School of Medicine.

All participants will undergo an MRE examination within four weeks before intestinal resection according to clinical diagnostic standards. The surgical

method and the extent of intestinal resection will be determined through multidisciplinary consultation, strictly following clinical guidelines. Patients will be assigned to either the training or testing group based on their hospital of origin. Patients from the First and Sixth Affiliated Hospitals of Sun Yat-sen University will be assigned to the training group, while the others will be assigned to the testing group.

For enrolled patients, the study will collect clinical baseline information, serum and fecal test indicators, MRE imaging data, and surgical specimens (five tissue samples per patient). By integrating laboratory tests, imaging data, and pathological scoring of resected intestinal specimens, we aim to develop and validate the artificial intelligence model.

All collected participant data and surgical specimens are obtained from routine clinical diagnosis and treatment processes and will only be used for this study. Relevant information will be strictly confidential. After the study, collected intestinal tissue specimens will be stored as paraffin-embedded sections at the respective treatment centers.

3. Risks and Discomforts

This study is an observational clinical study with a low probability of study-related risks. The preoperative MRE examination is part of standard clinical diagnosis and will assist in a comprehensive assessment of your condition, helping clinicians determine the surgical approach and the extent of intestinal resection.

However, a small number of participants may experience allergic reactions to the contrast agent used in MRE. We will carefully review your allergy history before the examination. If an allergic reaction occurs during the procedure, we will immediately terminate the examination and provide appropriate treatment following clinical protocols. Other potential risks will also be thoroughly assessed and managed to ensure your safety.

4. Benefits

This study only collects clinical data and surgical specimens obtained during your routine medical treatment. Participation in this study does not provide

direct personal benefits or improvements in disease prognosis. However, we hope this research will contribute to medical advancements, leading to improved diagnostic tools and treatment methods for a broader patient population.

5. Costs

This study follows standard clinical diagnostic procedures and will not impose any additional medical costs on you.

6. Privacy and Confidentiality

If you decide to participate in this study, your personal data will be protected according to the **Personal Information Protection Law of the People's Republic of China**, **Cybersecurity Law of the People's Republic of China**, and **Data Security Law of the People's Republic of China**. Your participation and personal information will be kept confidential. Your surgical specimens will be labeled with a study ID instead of your name. Identifiable information will not be disclosed to individuals outside the research team without your consent.

All study personnel and the study sponsor are required to maintain the confidentiality of your identity. Your records will be securely stored and only accessible to authorized research personnel. Government authorities or the ethics review committee may review your records when necessary to ensure compliance with study regulations. Any published study results will not disclose your personal information. If study data are transferred to other countries or regions, appropriate protective measures will be implemented in accordance with relevant legal requirements.

7. Compensation

As this is an observational study, the probability of research-related injury is low. However, we have arranged appropriate insurance coverage for participants. If any study-related injury occurs, compensation will be provided according to the terms of the insurance policy.

You may choose not to participate in this study or withdraw at any time by notifying the researcher. Your withdrawal will not affect your medical treatment or rights.

If necessary, the study physician may terminate your participation due to non-compliance with the study protocol, study-related adverse events, or other reasons.

If new information arises that may affect your willingness to continue participation, the researcher will inform you, and you may be required to sign a new informed consent form.

If you have any questions regarding this study, experience any discomfort, or have concerns about your rights as a participant, you may contact _____ (researcher) at _____(phone number).

This study has been reviewed and approved by the Ethics Review Committee of the First Affiliated Hospital of Sun Yat-sen University. The ethics committee can be contacted at 020-87338035.

Informed Consent Signature Page

I have read this informed consent form.

I have had the opportunity to ask questions, and all my questions have been answered.

I understand that participation in this study is voluntary.

I may choose not to participate or withdraw at any time without any consequences.

If I require other treatment or do not comply with the study protocol, the researcher may terminate my participation.

If new information arises, the researcher will promptly inform me, and I may need to sign a new informed consent form.

I will receive a signed copy of this informed consent form.

Participant's Name: _____

Participant's Signature: _____

Date:_____

I have accurately informed the participant about this study. The participant has read this informed consent form and had the opportunity to ask questions. I confirm that the participant voluntarily agrees to participate.

Researcher’s Name: _____

Researcher’s Signature: _____

Date:_____