The Effect of Intestinal Microbiota Transplantation for Inflammatory Bowel Diseases (IBD)

Date: **2017.05**

Informed Consent Form

Respected volunteer:

We are honored to invite you to take part in the research: the clinical efficacy of intestinal bacteria transplantation combined with traditional drugs treatment for inflammatory bowel diseases patients. This study will be carried out at the Zhongshan Hospital Affiliated to Xiamen University. We plan to recruit 30 volunteers to join in. This study has been examined and approved by the ethics committee of the medical school of Xiamen University.

The part of this article contains the rules and regulations, and in order to protect the rights and interests of the patients participating in the study. This article has been reviewed and agreed by the ethics committee.

Why should we carry out this study?

Background: There are many limitations in the current treatments of Inflammatory Bowel Diseases(IBD), including Ulcerative Colitis（UC） and Crohn's Disease(CD). Some patients have no or little reaction to the drugs. Now more and more scientists realized that the intestinal microbiota is closely associated with the development of Inflammatory Bowel Diseases. In recent years, a retrospective study showed that the

overall efficiency of intestinal microbiota transplantation for IBD was 79%, the overall remission rate was 43%, which opened a new chapter in the treatment of IBD. So the Standardized Intestinal Microbiota Transplantation is considered to be simple but effective emerging therapies for the treatment of IBD.

Research purposes：Aim to determine the efficiency, durability and safety of Intestinal Microbiota Transplantation for Inflammatory Bowel Diseases(IBD) patients, and further to explore which major bacteria may effect in this project.

Research area:18-65 years old Inflammatory Bowel Diseases(IBD) patients who had drug dependence or recurrence

How does the study going on?

Investigators plan to make the microorganisms from the fecal of the health into intestinal bacteria suspension through an intelligent processing system, and transplant it into the intestine of patients. All the patients will continue the routine therapy.

What should I do in the study?

Before you participate in the study, a specialist will collect your medical history to assess whether you are suitable for this study. If you are suitable for the study, you could sign the informed consent form and participate in the study or reject to participate in the study.

Do I have any other treatment options?

You can choose：

- Do not participate in this study and continue the routine treatment.
- Participate in other studies.
- Reject any treatment.

Please inform your doctor about your decision.

How will this study affect my life?

We will assess your disease status. If you are suitable for the study, we will treat you with intestinal microbiota transplantation and follow up for 12months On the basis of your informed consent form. Follow up may be inconvenient for your life. If you have any questions about the study, please consult the doctor.

What are the risks and adverse effects of participating in this study?

You may have an adverse effect during the study. We will monitor any adverse effects of all patients in the study. Intestinal microbiota transplantation is a relatively safe medical technique. There have been no reports of serious adverse effects so far. Short term adverse effects and complications include abdominal discomfort, abdominal distension, diarrhea, constipation, vomiting, short term fever, enteric bacterial infection, perforation and bleeding caused by endoscopic operation. We will recruit volunteers strictly according to the inclusion criteria , monitor and deal with adverse effects that may occur. The endoscopic operation will be completed by physician with rich experience of endoscopic

operation. The long-term risk includes: change of the body caused by intestinal microbiota change like obesity, diabetes, cancer and even personality changes, etc. In order to avoid these long-term risks, we will inform the patients in detail the risks and screen the donor strictly to ensure your safety to the greatest extent. Although we have taken the preventive measures mentioned above, there is still a possibility of adverse effects even serious consequences (including death) due to the complexity of medicine, individual differences.

All in all, we have undergone the study after examination and approval of the ethics committee and will get your informed consent form before it began. We will try our best to minimize the risk of the study as far as possible.

What is the reward for participating in this study?

We will exempt you from the cost of donor recruitment, acquisition of intestinal microbiota about 3000 yuan/case.

Is the my personal information confidential?

Your medical records will be kept in the hospital. The investigators, the authorities, and the ethics committee will be allowed to look up your medical records. Any public report about the results of this study will not disclose your individual identity. We will make every effort to protect the privacy of your personal medical information within the scope of the law. Your personal and medical information will be kept confidential and kept

in a safe and reliable place. You can consult the personal information, and if necessary, the information can be modified any time. When you sign this informed consent form, you agree that you agree that personal and medical information is used in the situation described above.

You sign this informed consent form only when you agree your personal and medical information will be used described above.

Do I have to take part in the study?

It is voluntary to participate in this study. You can refuse to participate in the study or quit research without any reason anytime. The decision will not affect your future treatment. If you decide to withdraw from this study, please notify the doctor in advance. In order to ensure your safety, you may be asked to carry out related inspections, which is beneficial to the protection of your health.

The researchers declared:

I confirm that the volunteer has been well informed of the details of this study, especially the risks and benefits that may arise from this study. If you have any questions related to this project, welcome to contact us anytime, and the phone number is +860592-22590151.

Signature of the research:_____ Date:_____

The volunteers agreed to declare that:

I have read the introduction of this study mentioned above, and I

have a full understanding of the risks and benefits that may arise from this study. I participate in this clinical voluntarily.

I agree□do not agree□ with that my medical records and pathological specimen in this study will be used for other study.

Signature of the subject:_____ Date:_____

Or signature of the legal representative (if there is):_____

Date:_____