

Study on Effect of Intestinal Microbiota Transplantation in Chronic Hepatitis B

Date: 2017-06-28

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 antiviral treatment for chronic hepatitis B patients. This study will be carried out at the Zhongshan Hospital Affiliated to Xiamen University. We plan to recruit 60 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: intestinal microbiota involved in maintaining normal physiological function and intestinal immune function. Many studies have found that human intestinal microbiota closely related to immune response. It has been confirmed that the intestinal microbiota of chronic hepatitis B patients is significant different from healthy people. Han-Hsuan Choua, et al have showed that gut microbiota contribute to the age dependence of HBV immunity in a hydrodynamic transfection mouse model. Intestinal microbiota transplantation is an effective way to reconstruction of the microecology of intestine which has been included in the American Medical Guide to treat *Clostridium difficile* infection.

Research purposes: treat chronic hepatitis B patients with antiviral therapy combined with intestinal microbiota transplantation.

Research area: 18-65 years old chronic hepatitis B patients undergoing antiviral therapy.

How does the study going on?

We 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 original antiviral

therapy.

What should I do in the study?

Before you participate in the study, a specialist will analyse 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?

In addition to antiviral treatment, there is no special effective method for the treatment of chronic hepatitis B. 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 6 months. 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 include: change of the body that may 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.

Therefore, 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 researchers, the research authorities, and the ethics committee will be allowed to look up the 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 the 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 call 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 voluntarily participate in this clinical.

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:_____