Informed Consent Form

Chinese Chronic Liver Failure Consortium Acute-on-Chronic Liver Disease and Failure Study ——a Prospective Multi-center Study in China, the Largest Hepatitis B Virus High-endemic Region

Clinicaltrials.gov ID: NCT02457637

2014.11.30

Informed Consent Form

Dear patient

We invite you to participate in this prospective, multi-centered study. The study will be conducted jointly by Renji Hospital, School of Medicine, Shanghai Jiao Tong university and other top tertiary hospitals including your hospital. It is estimated that 3,000 participants will participate voluntarily. This study has been reviewed and approved by the ethics committee of the Renji Hospital, the leading hospital.

Some of the content covered in this article is determined by regulatory requirements, and this consent has been reviewed and approved by the Ethics Committee in order to protect the rights of patients participating in the study.

Why do we launch this study?

To study the clinical characteristics of patients with chronic liver disease admitted to hospital for complications of cirrhosis, in order to establish a standard of diagnosis and treatment for Chinese patients with chronic liver disease.

How will this study be conducted?

1. This study will conduct regular and comprehensive disease assessments for eligible patients with cirrhosis during hospitalization and provide appropriate standardized treatment. In this study, patient's blood and urine specimens need to be taken, remaining blood and urine specimens are taken in addition to the specimens required for the laboratory examination.
2. Monthly outpatient follow-up and 3-month telephone follow-up after discharge.
3. Once the condition has changed during the follow-up period, patients could contact the doctor promptly via WeChat or follow-up personnel to give priority to the visit or hospitalization.

What should I do in the study?

1. This study will last for 3 years and eligible participants will be followed-up by outpatient visit or telephone.

2. During hospitalization, the doctor responsible for this study will set up a WeChat number for your cellphone and invite you to join WeChat group to ensure direct contact between patients and the follow-up personnel.

3. Leave at least two phone numbers that can be directly contacted to you and your immediate family members.

4. Once discharge, you will be taken care of by the residents for the next three years, including the following:

1) WeChat will be notified by month to the outpatient clinic and dispensing (you will be notified one week in advance)

2) Appointment arrangement and make sure your appointment with your physician or other specialists.

3) Regular blood test or ultrasound according to your disease condition.

4) If there is a change of disease condition after discharge, please contact the doctor through WeChat in time. We will help you arrange a next-day outpatient clinic visit or emergency visit as soon as possible to assess your condition. If you need to be hospitalized, you will be

admitted to hospital through the Green Channel.

5) If you are unable to see a doctor for personal reasons, we will call you every three months to keep up with your condition and give probable advices.

How will this participation affect my life?

Through this study, you will receive a regular three-year follow-up from a specialist. Your doctor will master your disease condition so that you can acquire better treatment and faster recovery. This will not increase any extra expenses, and will not cause any inconvenience to your life.

What benefits can I get from this research?

1. You will be taken care of during your hospitalization and we will make a dynamic assessment of your disease condition.

2. During the follow-up period, doctors will inform your time of appointment for outpatient clinic once a month and help you make an appointment.

3. If your disease condition changes during the follow-up period, you can tell your familiar doctor in time.

4. If you need to be hospitalized due to changes of disease condition during the follow-up period, you can have the preferential to hospital through the green channel.

5. The information obtained from this study will help to determine which treatment can be more effective and safer.

Is my personal information confidential?

Your medical records will be kept in the hospital. Researchers, research authorities, and ethics committees will be allowed to consult your medical records.

Personal and medical information about you and related dependents will be kept confidential and kept in a safe and secure place. At any time, you can request access to your personal information (such as your name and address) and modify it if necessary.

By signing this Informed Consent, you agree that your personal and medical information will be used in the circumstances described above.

7. Do I must have to participate in the research?

Participation in this study is completely voluntary and you may refuse to participate in the study or opt quit the study at any time during the course of the study, without any reason. This decision will not affect your future treatment. If you decide to quit this study, please inform your research doctor in advance.

Subject agrees to declare:

I have read the above introduction to this study and have a comprehensive understanding of the risks and benefits that may arise from participating in this study. I voluntarily agree to participate in the clinical study described in this article.

Subject signature: _____

Subject contact number:_____; Date: _____

Signature of legal principal (if any):_____;

Legal principal and patient relationship: _____

Statutory entrusted contact number:_____; Date: _____

The investigator statement: I have confirmed that the details of the study have been explained to the patient, especially the risks and benefits that may arise from participating in the study.

Researcher's signature: Date: _____

Researcher Tel:021-63200874 Contact:

Li Hai