The Chinese University of Hong Kong

Faculty of Medicine

Department of Medicine and Therapeutics

Patient Information Sheet of ACLD_REG Study

Study title: Natural history of advanced chronic liver diseases and factors associated with hepatic events – a registry study (ACLD_REG study)

Background

Advanced chronic liver disease (ACLD) creates significant burden to the global healthcare system. It contains a spectrum from compensated ACLD to decompensated cirrhosis in which prognosis differs significantly. Many efforts have been paid to identify ways to prevent liver decompensation so as to improve clinical outcomes such as the use of medications. Early detection and prediction of the risk of liver decompensation is also important. Examples may include the use of vibration-controlled transient elastography (VCTE) or biomarkers. However, all these measures either remain premature for routine clinical practice or inapplicable across all liver disease aetiologies.

Purpose

The aim of this study is to understand the natural history of ACLD and identify any factors associated with liver events.

Why should I participate in this study and how?

Since you have a diagnosis of ACLD, you are invited to participate in this study. You will undergo regular VCTE examination and receive blood tests yearly until year 10. You will be followed up in our hepatology clinic at Prince of Wales Hospital. At each visit, any observed or reported symptoms and clinical events will be assessed and documented. 20ml of blood will also be taken at every year, and stored for 15 years for future genetic and biochemical research. A direct telephone line will be provided so that you can report any adverse events between the scheduled visits.

Subject withdrawal

A patient must be withdrawn from the study if he/she withdraws consent. Subjects who (1) experience adverse events, or (2) have pre-existing violation of entry criteria may remain in the study unless the investigator determines that it is not in the subject's best interest to continue. Subjects who withdraw from the study are invited to continue his/her usual clinic visit for documentation of any study endpoints until year 10.

What are the possible benefits of taking part?

We hope that the serial use of VCTE to monitor the liver and spleen stiffness, as well as development of novel biomarkers, will be useful in predicting liver decompensation and death in patients with ACLD. Assessment is carried out on every visit to document any clinical events by medical history taking, physical examination, laboratory parameters, and reports of adverse events and/or serious adverse events. In addition, by receiving serial liver and spleen stiffness monitoring, we will be able to detect any significant changes in the parameters to prompt

timely assessment. We hope that the data from this study can be used to plan for a better management algorithm in future for patients with ACLD.

What are the potential risks and discomforts?

There is minimal discomfort in blood taking. VCTE is a non-invasive investigation without risks.

Numbers of subjects involved in the trial

Around 500 subjects will be recruited.

Alternatives

You may choose not to participate in this study.

Subject Cost and Payment

There is no additional cost or payment for your participation in this study.

Confidentiality

Your data will be kept strictly confidential and will only be assessed by a designated adjudication committee, also the monitor(s), the auditor(s), the IRB/IEC, and the regulatory authority will be granted direct access to the subject's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the subjects. The study data will be stored for 15 years and permanently deleted afterwards. If the study results are published, the subject's identity will remain confidential.

Patient Rights

You can contact our investigator Dr. Jimmy Che-To Lai or study coordinators (Tel 3505-4205) for questions related to the present study. You can also dial the hotline of Joint the Chinese University of Hong Kong --New Territories East Cluster Clinical Research Ethics Committee at 3505 3935 for patient right-related questions. Also, Joint Chinese University of Hong Kong – New Territories East Cluster as one of the authorized partied to access the subjects' records related to the study for ethics review purpose. You are assured that refusal or early discontinuation of participation in the study will not jeopardize the quality of your care.

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I _____, have reached the age of 18. I hereby give my consent to participate in the above clinical trial. I understand the study details. Signing this consent form indicated that I have read this consent, that my questions have been answered to my satisfaction, and that I voluntarily agree to participate in this research study. I will receive a copy of this signed consent form.

I acknowledge that the purpose of the undertaking and methods of the study have been fully explained to me. Moreover, I understand and have been explained the advantages, disadvantages and risks involved in the study. My personal information will be kept confidential. I understand that this study has been approved by the Joint the Chinese University of Hong Kong --New Territories East Cluster Clinical Research Ethics Committee. Also, Joint Chinese University of Hong Kong – New Territories East Cluster as one of the authorized partied to access the subjects' records related to the study for ethics review purpose.

I give my consent to this clinical study at my own will. I understand that I can withdraw from the study at any time and this will not have any consequence on my subsequent treatment.

Subject's name (in block letters):_____

Subject's signature:_____ Date:_____

Witness's name (in block letters):_____

Witness's signature: _____ Date:_____

Investigator's name (in block letters):_____

Investigator's signature: _____ Date:_____