The Chinese University of Hong Kong

Faculty of Medicine

Department of Medicine and Therapeutics

Patient Information Sheet of BASS_HCC Study

Study title: Validation of Baveno VII criteria and spleen stiffness measurement on outcome prediction in patients with hepatocellular carcinoma (BASS_HCC study)

Background

Hepatocellular carcinoma (HCC) burdens the global healthcare system with a drastic increase in incidence by 70% from 1990 to more than 700,000 cases in 2019. Underlying liver diseases has an important impact on the outcome in patients with HCC. Despite HCC can be curable at early stages with preserved liver function, there are possibilities of HCC recurrence and liver decompensation afterwards.

Vibration-controlled transient elastography (VCTE) allows liver and spleen stiffness measurements (LSM and SSM) and was shown to correlate with the degree and prognosis of various liver diseases. Yet its use in patients with HCC still requires validation.

Purpose

The aim of this study is to assess the validity of LSM and SSM in predicting liver decompensation, HCC recurrence and liver-related death in patients with HCC who are to receive curative treatment.

Why should I participate in this study and how?

Since you have a diagnosis of HCC, you are invited to participate in this study. You will undergo VCTE and oesophagogastroduodenoscopy (OGD) examinations before you receive the treatment for HCC. After the curative treatment of HCC, you will be serially monitored with VCTE every six months until month 60, and OGD at month 12, month 36 and month 60 at Prince of Wales Hospital as routine care. At each visit, any observed or reported symptoms and clinical events will be assessed and documented. 20ml of blood will also be taken at 6 months, and stored for 15 years for storage of 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A patient must be withdrawn from the study if he/she withdraws consent.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 month 60.

What are the possible benefits of taking part?

We hope that the serial use of LSM and SSM will be effective in predicting liver decompensation, HCC recurrence and death in patients with HCC. 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 LSM and SSM 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 HCC.

What are the potential risks and discomforts?

There is minimal discomfort in blood taking. VCTE is a non-invasive investigation without risks. Major complications of OGD include bleeding and perforation but the major complication rate is overall less than 0.1%.

Numbers of subjects involved in the trial

159 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:_____