Adjuvant Radiotherapy for Resected Hepatocellular Carcinoma With MVI

NCT 04891874

2015-08-01

Informed consent form

Name: Hospital ID:

This is a prospective clinical trail testing the efficacy of stereotactic body radiotherapy as adjuvant therapy for resected early stage hepatocellular carcinoma(HCC) patients. The adjuvant therapy, including radiotherapy, aims to lower the rate of early relapse after surgery for patients with HCC. This study was approved by the ethics committee of Eastern Hepatobiliary Surgery Hospital (EHBH). The study protocol conformed to the principles of Declaration of Helsinki (1983). All participants have following rights.

1. You have the rights to learn information about what method we will apply to treat you. As an early stage HCC patient, you have the opportunity to receive a surgery in EHBH to remove the tumor from your liver. During the operation, you will probably be marked with fudicial marker to figure out where tumor may infiltrate normal liver tissue. After surgery, as you recovered smoothly, you will have the right to participate this study. If you are willing to join the study, you will be randomized into two groups, stereotactic body radiotherapy(SBRT) group or surgery alone (SA) group.

2. If you are put foward to the SBRT group, you will receive a cycle of SBRT as adjuvant therapy. SBRT was safe treatment for participants. The

dose and volume of radiation will be set by professional doctor in charge.

3. Before SBRT, you will receive thorough examination including blood test, liver function, electrocardiograph. CT scan will be applied to learn the information about your liver after surgery. Once any parameter dose not meet the standard for SBRT, you will not be put forward to therapy. If it happens, you will drop from the study and return to the follow-up team.

4. If you are randomized into the SA group, you will not receive SBRT and just get follow-up in out-patient services.

5. For all the participants, in both groups, have the rights to withdraw form the study, at any moments, for any reasons.

6. For all the participants, if adverse events occurred, will receive support and care from the care unit, which are gathered with experienced health workers.

While all above information are learned by you, please think carefully and make your choice.

☐ Yes, I hope to participate in the study.

☐ No, I am not ready to participate.

Signature:

Date: