Division of Liver Transplantation

Department of Surgery

The University of Hong Kong

Patient Information Sheet and Consent Form

Initial Experience with Stereotactic Body Radiotherapy for Intrahepatic Hepatocellular Carcinoma Recurrence after Liver Transplantation

Version 1.0 (25th March, 2020)

Purpose of study

The current study is conducted to evaluate the safety and efficacy of stereotactic body radiotherapy (SBRT) for the treatment of graft hepatocellular carcinoma (HCC) recurrence after liver transplantation.

Background information

Since the implementation of the Model for End-Stage Liver Disease (MELD) allocation system, patients enlisted for HCC have been given increased priority for cadaveric grafts. Adoption of extended criteria also largely expanded the recipient pool. With increasing numbers of liver transplants performed for HCC, recurrence is more frequently encountered. One-third of post-transplant recurrence is confined to the liver graft. In this context graft hepatectomy offers chance of cure, but is technically challenging due to hostile adhesions surrounding vital portal structures. Infective complications are not uncommon after such ultra-major operation in an

immunocompromised host. The demand for a safe and effective treatment modality is desperate.

SBRT, a precise delivery of conformal external beam irradiation, has been shown to be safe and effective for the treatment of primary HCC. SBRT has become an appealing alternative to surgery in patients with inadequate liver function. However, the role of SBRT for HCC recurrence in a liver graft remains unclear. There is no literature to report the oncological benefits and the potential toxicity to the liver graft.

Why have you been chosen for the study?

You have been chosen for the study because you have received SBRT for intrahepatic HCC recurrence after liver transplantation.

Methods of study

A retrospective study was conducted. From 2012 to 2018, 6 patients with intrahepatic HCC recurrence after liver transplant were treated with SBRT at Queen Mary Hospital, the University of Hong Kong. The primary outcome was time to overall disease progression and secondary outcomes were time to local progression and best local response, as assessed with the Modified response Evaluation Criteria for Solid Tumours (mRECIST) criteria. Patients were monitored for treatment related toxicities and graft dysfunction.

Any disadvantages or risks in participating in the study

No additional risk is incurred by participating in the study.

Any benefits in participation in the study

Your participation in the study will provide further insights into the role of SBRT in managing post-transplant HCC recurrence.

Confidentiality

You have the rights to access to personal data and publicly available study results, if and when needed.

Under the laws of Hong Kong (in particular the Personal Data (Privacy) Ordinance, Cap 486), you enjoy or may enjoy rights for the protection of the confidentiality of your personal data, such as those regarding the collection, custody, retention, management, control, use (including analysis or comparison), transfer in or out of Hong Kong, non-disclosure, erasure and/or in any way dealing with or disposing of any of your personal data in or for this study. For any query, you should consult the Privacy Commissioner for Personal Data or his office (Tel No. 28272827) as to the proper monitoring or supervision of your personal data protection so that your full awareness and understanding of the significance of compliance with the law governing privacy data is assured.

By consenting to participate in this study, you expressly authorize

- The principle investigator and his research team and the ethics committee (Institutional Review Board of the University of Hong Kong / Hospital Authority Hong Kong West Cluster) responsible for overseeing this study to get access to, to use, and to retain your personal data for the purposes and in the manner described in this informed consent process; and
- The relevant government agencies (e.g. the Hong Kong Department of Health), to

get access to your personal data for the purposes of checking and verifying the integrity of study data and assessing compliance with the study protocol and relevant requirements.

Compensation

No compensation of any kind will be provided for participation in this study

Obtaining additional information

You are encouraged to ask questions at any time during the study. If you have any questions about this research study, please contact Dr. AU Kin Pan at 22553025.

Voluntary Declaration

I understand that the decision to participate in this study is voluntary. If I refuse for any reason and at any time to participate in the study, my treatment and care will not be affected in any way. I have read and have been informed of the forgoing information, and I have the chance to discuss fully with the investigators about this study. I consent voluntarily to participate as a subject in this study.

Consents and Signature

_____	_____	_____
Name of patient (in block letters)	Signature of patient	Date

_____	_____	_____
Name of investigator (in block letters)	Signature of investigator	Date

_____	_____	_____
Name of witness (in block letters)	Signature of witness	Date