Government of South Australia
SA Health

Royal Adelaide Hospital

Participant Information and Consent Form

TITLE: Fiducial **I**mage guided **S**tereotactic ablative body radiotherapy (SABR) for **H**epatocellular carcinoma **A**fter Interventional **R**adiology treatment (TACE) (**FISHAR** trial)

Background

You are invited to participate in a research study because you have been diagnosed with hepatocellular carcinoma (HCC), which at this stage cannot be surgically removed and previous transarterial chemoembolization (TACE) has been unsuccessful.

This patient information sheet contains detailed information about the research study that you have been asked to join. Please read this information carefully and ask questions about anything that needs further explanation. Your doctor will also describe this study to you and answer your questions. Please take your time to make a decision, and discuss this study with your doctor, family members and friends, if you feel it is necessary. You may take home an unsigned copy of this form to review before making your decision.

Your participation in this study is completely voluntary, and whether you take part or not, your medical care and the services that you receive, will not be affected in any way.

Aims of the Trial

This study is looking at patients with locally advanced liver cancer that cannot be surgically removed and is still present after previous TACE treatment. The treatment option for this trial is Stereotactic body radiotherapy (SABR), a technique that delivers high dose radiotherapy fractions to the precise location of the tumour. This technique minimizes radiation exposure to the surrounding normal liver tissue.

The aim of this study is to assess efficacy and safety of SABR for patients that have had an unsuccessful first round of TACE. SABR is currently being used in the treatment of other cancers, including prostate cancer. We hope SABR will provide an alternative treatment option that may be better at controlling locally advanced liver disease, compared to repeating TACE procedures. To allow us to concentrate the radiation beams to tumour, whilst minimising toxicity to surrounding non-tumorous tissue, we will be inserting gold markers (called Fiducials) to mark the borders of the tumour. This will act as a target and assist in maximising the radiation aimed at the tumour while minimising the radiation to its surroundings. We are doing this study in the hope that we can optimise management treatment of patients with HCC.

This research will be conducted according to the NHMRC National Statement of Ethical Conduct in Human Research, 2007 and has been approved by the Human Research Ethics Committee of the Royal Adelaide Hospital.

Pre-treatment

Before commencing SABR treatment we will need to perform routine tests to ensure that you are eligible to have this treatment safely. This may include blood tests and imaging, however, it is likely that you will already have completed these as part of your standard treatment. If you are eligible and agree to participate in this trial, you and your doctor will meet to discuss the trial, review your symptoms, medication and investigations. You may also need to come in on another occasion to have some small metallic seeds inserted in to the area around the tumour via a flexible camera (endoscopy). Your doctor will then organise for you to have a radiotherapy planning session that will require a CT scan. Measurements will be taken and approximately three small tattoos will be drawn on the skin. Once a radiotherapy plan has been designed, you will need to come to the treatment area for a test run, where the treatment machine will move into various positions but not actually deliver any radiation. This is to ensure that the beam angles designed by the radiotherapy plan are usable.

Treatment Period

The details of radiotherapy planning will be provided by your radiation oncologist. The SABR treatment will take place over three sessions, delivered twice per week. Each session will take up to one hour. In all, it should take approximately a week and half to complete the course of treatment. Radiotherapy uses high energy x-rays to destroy cancer cells while doing as little harm as possible to normal cells.

Follow-up Period

Once radiotherapy has been completed, you will be followed up at regular three monthly intervals for a minimum of two years. During this time, you will require a number of CT scans and blood tests to determine the progress of the cancer.

Your commitments

You must agree not to use any prescription medication during the study, without first checking with your doctor. You must agree not to participate in any other research study while participating in this study. You must have stopped taking any research medications at least three weeks before enrolling in this study. You attendance will be required at the Royal Adelaide Hospital for your medical review and radiotherapy.

Benefits to you

We cannot guarantee or promise that you will receive any direct benefits from participating in this study. However, the success rate of repeat TACE treatments can be low and there is increasing evidence that SABR treatment may be more effective in controlling disease progression. In the future, it is hoped that SABR will be routinely made available for HCC patients, either as an alternative to TACE or for patients that have had unsuccessful TACE

procdeures. It is possible that a benefit to you may include control of the cancer within the liver.

Personal Costs

There will not be any financial cost to you for participating. There are no additional costs associated with participating in this research project, nor will you be paid.

Compensation

If you are injured as a direct result of taking part in this study, hospital care and treatment will be provided by the public health service at no extra cost to you. The study has been indemnified by SA Health. Irrespective of any treatment provided you should also understand that you have the right to seek compensation through the legal system.

Your participation is voluntary

Taking part in this study is your choice. You can decide not to participate, or leave the study at any time, without penalty or loss of benefits to which you are otherwise entitled. If you leave the study, the standard of medical care you receive will not be affected in any way.

During the study, you will be informed promptly of any new information that may affect your willingness to continue in the study.

Please note that once inserted, the fiducial markers used cannot be removed without undergoing a surgical procedure. Your doctor will discuss this with you.

Are there any risks involved?

COMMON, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, more than 20 may have:
• Tiredness • Swelling, redness, and/or sores in the area of radiation

OCCASIONAL, SOME MAY BE SERIOUS In 100 people receiving radiation therapy, from 4 to 20 may have:
• Nausea, vomiting • Pain • Internal bleeding • Diarrhea, passing gas, blockage of the stomach • Broken bone • Bruising, bleeding

RARE, AND SERIOUS In 100 people receiving radiation therapy, 3 or fewer may have:
• Liver damage which may cause yellowing of eyes and skin, swelling

Alternatives to participation

If you decide not to participate in this study the standard of care option is to have repeat TACE procedures.

Confidentiality, privacy and disclosure of information

Any research results obtained from this study may be published in a variety of formats, including conference presentations and journal articles. Your identity would not be revealed and your identity and privacy will always be protected.

A description of this clinical trial will be available on www.anzctr.org.au as required by the Ethics Committee. This web site will not include information that can identity you. At most, the web site will include a summary of the results. You can search the web site at any time.
We will be collecting and storing information, including your age, gender, medical history, treatment regime and results of relevant tests (including blood, radiology and biopsy results). During the course of the study we will keep your personal details, along with the data we collect, so that we can track your progress. When the study is complete (after about 18 months) all personal details will be removed and a study number will be assigned. Your data will be stored electronically in the department of Gastroenterology and Hepatology at the Royal Adelaide Hospital. It will be password protected. The data will be kept for a maximum of 15 years, after which time it will be erased/destroyed.

In addition to the processes described above, data may otherwise be discoverable through processes of law or for assessing compliance with research procedures. You have a right to access the information collected and stored by researchers about you. You also have a right to request that any information with which you disagree be corrected.

Publication

It is usual for a number of years to pass before the final results of this type of study are available. These are published in medical journals that are available to the public. You should feel free to ask your doctor about this. It is possible that the results may not be published for scientific, commercial or other reasons.

Whom can I contact if I have questions?

We encourage you to call us if you have any questions or concerns. You can contact the study doctor: Dr Hien Le (08) 8222 4797.

Ethics contact

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Complaints contact person: The Royal Adelaide Hospital Research Ethics Committee Chairman on (08) 8222 4139.

Royal Adelaide Hospital Gastroenterology/Hepatology Biobank
Participant Consent Form

Part 1: Participant Consent

The nature, purpose and risks of the research project have been explained to me. I understand them and agree to take part. I also understand that I may not benefit from taking part in this study.

I,……..
(please print your full name)

have been provided with a Participant Information Sheet and agree to participate in FISHAR

I give permission for the FISHAR team to access my current and future medical records from the Royal Adelaide Hospital, pathology laboratories and from any public or private health care facility that I have attended concerning my gastroenterological diagnosis and/or treatment.

I (the investigator) confirm that to the best of my knowledge, the participant understands the information provided, the implications of the information and the participant will be provided with a copy of this document.

Investigator full name:…… Date:……..

Investigator signature:…… Date:……..

Participant Signature:……Date:……..

Independent Witness (if required) Name……..

Signature…… Date:……..