Imperial College London

Imperial College Healthcare NHS
NHS Trust

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PATIENT INFORMATION SHEET

Title of Research Project: Profiling for biomarkers in liver malignancies
Principal Investigators: Professor Simon Taylor-Robinson, Dr Shahid Khan
Study number: 09/H0712/82

Dear Sir or Madam,

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

This information sheet aims to explain the purpose of the study and what will happen to you if you take part. The later sections give you more detailed information about the conduct of the study.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for taking the time to read this information sheet.

Simon Taylor-Robinson
Professor of Translational Medicine
Department of Hepatology

Dr Shahid Khan
Senior Lecturer
Department of Hepatology

Introduction
The department of Hepatology & Gastroenterology at Imperial College London carries out research into many different diseases of the liver. These diseases include liver cancer, infections and inflammatory diseases. Our work involves staff at St Mary's Hospital, Hammersmith Hospital and Charing Cross Hospital. We also work with partner hospitals elsewhere in the UK.

What is the purpose of this study?
Liver diseases are an increasingly common problem in the UK and around the world. It is not always clear why this is. Little is understood about why some people develop some liver diseases and others do not do so.

We wish to compare patients with no liver disease to those with benign (non-cancer) liver disease and to those who have developed a cancer.

Liver cancer can be difficult to diagnose as it doesn't always cause symptoms in the early stages. This can delay diagnosis. Another difficulty is that some types of benign (non-cancerous) liver disease can appear cancerous on current tests. This can cause uncertainty and worry for patients.

This study will search for changes in DNA that might put someone at risk of developing liver cancer. DNA makes up the genes that control everything that goes on in the human body. It is found in almost every cell in the body, including many bloods cells. We will collect a small amount of DNA from your blood samples. We will then look at changes in the DNA that might cause or prevent liver tumours. We will also look for specific proteins and other chemicals in the blood, bile and urine. These may give clues about how cancer develops and also about possible new, more accurate, tests.

In summary, *our aims are:*
- *To understand more about why liver diseases, including cancer, develop*
- *To find new tests that may allow earlier and more accurate diagnosis*

Why have I been chosen?
You have been chosen because you are being seen in a clinic or other department that is working with us. The doctor or nurse looking after you has suggested that you may be suitable to participate in this study. We believe that it would be useful to include your urine, blood or bile in our study for analysis, (or if you are having an operation, some of the liver tissue that will be removed as a standard part of your operation).

When studying any disease it is also important to compare patients to others who do **not** have that disease. Therefore, we will also collect samples from consenting patients who have benign liver disease or *no liver abnormality at all.* In total, we hope to recruit just over 2,000 volunteers for this study.

In summary, *we are asking for volunteers from all of the following groups:*
- *Patients with NO liver problems at all who are being seen in hospital for non-liver issues*
- *Patients with benign (non-cancerous) liver diseases*
- *Patients with different types of liver cancer*

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still

free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive in any way.

What will happen if I take part? What do I have to do?
All patients who agree to participate will be asked to:

- Read and sign a consent form
- Provide a blood sample. This may be done at the same time as your routine blood tests in the clinic or arranged at another time. 16ml of blood will be taken (the equivalent of 3 teaspoonsful) with a needle from a vein.
- Provide a urine specimen in the provided container (about 10ml – the equivalent of 6 teaspoonsful)
- Allow us to collect some details from your medical records (in strict confidence)

The consent form highlights some of the key points about participating in this study. You will be asked to initial a number of paragraphs and sign & date the form. You will be given a copy of this form.

Some patients will be asked to fast completely before their blood test is taken. If this applies to you, the doctor or nurse will explain this to you. You will be asked not to eat anything from midnight until your blood test is taken. We will arrange an appointment for your blood test before 10am. You can drink water normally throughout. We ask you not to drink anything but water – particularly milk, tea, juice or coffee.

Unless you are due to undergo a specialist ERCP test, PTC test, operation or biopsy, no other samples will be taken. If you are due to undergo an ERCP, PTC, biopsy or operation we may ask for a further sample. Please see the next question for further information on this.

The whole study will take up to three years to complete, but your involvement would be much more limited. In total we estimate that your direct involvement in this study should take no more than an hour. Of course, this involvement will be slightly prolonged if you have to alter your diet for twenty four hours before giving your samples.

You will not have to attend any further extra appointments or undergo any other extra tests.

What if I am to undergo an ERCP test, PTC test, biopsy or operation?
If you are going to have an ERCP test, PTC test, biopsy or operation as part of your normal care, your doctor will have explained why and what this involves. You will **not** be given an ERCP test, PTC test, biopsy or operation as part of this study.

If you do undergo an ERCP or PTC test we can take an extra sample during the procedure. This involves collecting about 5ml of bile and/or pancreatic juice (1 teaspoonful). Collecting the bile or pancreatic juice does not involve any extra invasive procedure. There is no added risk to you in taking this extra sample.

If you do undergo a biopsy or operation it is highly likely that samples of your tissue will be sent to the lab for special tests. If the amount of sample taken is more than necessary for routine lab testing we would like to analyse the spare sample as part of this study. No extra tissue will be taken, other than that which is required for your biopsy or operation. You will not have to undergo any extra procedure. There will be no extra risk to your health in us using any spare sample in this way.

What will you do with the samples?
The samples will be studied in a variety of ways. We will analyse the proteins, DNA and other chemicals in them. We will compare the levels of these different chemicals in patients with different diseases with those who are healthy.

Sometimes it is necessary to send samples to external laboratories – in the UK or abroad – for specialist tests. Only anonymised samples would be sent to an external lab, no personal details or clinical details about your case would be shared.

What are the possible side effects of taking part? What are the possible disadvantages and risks of taking part?
As you will not receive any extra treatment we do not foresee any potential side effects.

Some patients may develop a bruise after giving a blood sample. This will heal naturally with no treatment. Of course, you may be having a blood test anyway as part of your normal clinic assessment.

You may find the restrictions on your diet a disadvantage. We anticipate no other potential risks.

What are the possible benefits of taking part?
We do not anticipate any direct benefit to you. However, the information we get may help improve the future diagnosis or treatment of people with liver disease. You will not be paid for participating in this study.

What if something goes wrong?
It is highly unlikely that anything will go wrong during your participation in this study.

Imperial College London holds insurance policies which apply to this study. If you experience serious and enduring harm or injury as a result of taking part in this study, you may be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Professor Simon Tayor-Robinson, contact details at top of this form). The normal National Health Service complaint complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Office

Will my taking part in this study be kept confidential?
All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it.

Our procedures for handling, processing, storage and destruction of their data are compliant with the Data Protection Act 1998.

It is unlikely that we will discover any information that is of direct importance to you or your family. If we do so, we will contact you and your GP to inform you of this. If you DO NOT wish us to contact you or your GP about any such information, please discuss this with the researcher. Your wishes will be recorded and observed.

What happens when the research study stops? What will happen to the results of the research study?
When the study stops we will analyse all of the results. The study will be written up and may be published in medical journals and presented at conferences. No patients will identifiable in any published results.

Our results will also be shared with the organisations and charities that support our work, including patient support groups. Again, no patients will be identifiable in any information that is shared with these groups.

If you wish to receive feedback on the study, you can contact us and we will send you a summary of the results and conclusions of the study. The contact details are listed below.

Any remaining samples will be kept securely, complying with rules set out in the Human Tissue Act. They may be used in future research projects that have received approval from an independent ethics committee. You would not be contacted again for further permission to use the samples in such future studies. Any samples kept beyond the end of this study may be held securely in a properly regulated biobank. The biobank will ensure that any samples are kept safely and are only used in ethically approved studies into human diseases. If you would rather that your samples were not used in this way, you may specify this on the consent form at Section 9.

Who is organising and funding the research?
Details of the people co-ordinating this study in your hospital are provided at the bottom of this information sheet.

This study is being organised by the Hepatology Department at Imperial College London, in co-operation with Imperial College NHS Trust (St Mary's Hospital, Hammersmith Hospital, Charing Cross Hospital). A number of other NHS hospitals around the UK are also collecting samples for this study.

This study is being funded by a number of charitable organisations. These include The British Liver Trust, St Mary's Paddington Charitable Trust and The Alan Moremont Memorial Fund.

Who has reviewed the study?
This study was given a favourable ethical opinion for conduct in the NHS by St Mary's Research Ethics Committee (Ref **09/H0712/82**).

Contacts for further information:
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Thank you for reading this information and considering participation in this study.
You are asked to retain this Patient Information Sheet for your future reference