Royal Free London NHS
NHS Foundation Trust

Royal Free Hospital
Pond Street
London
NW3 2QG

Tel: 020 3758 2000

Patient information:

Prospective Evaluation of AI R&D tool for patient stratification - Trial for Renal immuno-oncology model Experimental Evaluation (PEAR-TREE)

Introduction:

Over 13,000 people are diagnosed with kidney cancer every year in the UK, and every year the number is rising. The incidence of kidney cancer has doubled since the 1970s. The only real chance of cure is early detection and surgical removal of the tumour before the cancer spreads. If the cancer does spread outside of the kidney, then there are many different medications that can be offered to try to slow or even reverse this spread.

Currently, it is not always possible to know which patients with kidney cancer will respond to which drugs. This means that patients sometimes need to try a series of different treatments to find one that works for them. This may cause a delay in patients getting the right treatment, as well as meaning they might suffer side effects from medications that don't work.

A new diagnostic test has been developed by Pear Bio that uses a small tumour sample alongside a sample of blood that is placed in a device called an organ-on-a-chip. The organ-on-a-chip acts as a proxy for the patient so different treatment options can be tested without needing to expose the patient to those treatments. Various treatment options can be tested at the same time at Pear Bio's central laboratory. In the future, this could allow patients' oncologists to prescribe effective treatments for patients sooner.

If you have a kidney tumour and are having surgery, we are asking permission to take an additional blood sample and samples of your tumour (after it has been removed) to use in optimising Pear Bio's technology.

We will also ask for your consent to communicate long term health information about you with Pear Bio for the purpose of this study.

We will also ask for your consent to link your data to NHS Digital records or other NHS registries to find out how your health is in the future and to be able to contact you, should you be 'lost to follow-up'.

What is the purpose of the study?

The purpose of the study is to test and improve the organ-on-a-chip tool. Better understanding of how different tumours respond to treatments outside of the human body will allow us, in the future, to select treatments that are more likely to work for each patient and their tumour. This will allow future patients to get better treatments sooner, and avoid the side effects of treatments that will not benefit them.

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What will happen to me if I take part?

If our checks show you are suitable to join the study, we will give you a participant information sheet.

If you decide to participate in the study, you will be asked to consent. This can either be done by signing a consent form or electronically via an email link or app.

When you have surgery for your kidney tumour, we will take an additional sample of blood for the study. Following your surgery, we will use tissue from the tumour that is surplus for diagnostic purposes. The tissue from your tumour will be analysed in different ways, including genetic analysis of the cancer. This helps us understand more about the tumours in our study. If the tumour is found not to be a cancer, then you will be withdrawn from the study.

Long term health data from your medical records will be shared with researchers at Pear Bio and regulators.

You can change your mind about participation in the study at any time; this will not affect your current or future medical care.

What are the possible risks associated with the study?

The blood sample required for the study does not lead to any significant additional risk to you. There may be some bruising associated with providing the blood sample, and very occasionally, patients may feel faint, dizziness or discomfort.

Collection of the tumour tissue will happen in the laboratory after it has been removed as part of your routine surgical care. It does not pose any additional risk to you.

Where will my donated samples be kept?

Any samples taken that are transferred will be done so securely and in line with the Human Tissue Act (2004) and the Data Protection Act (2018) and any other subsequent regulations.

All samples donated will be transferred from Royal Free Hospital to Pear Bio's laboratory via Royal Free/UCL BioBank.

After the study, blood and tumour samples may be retained by Pear Bio for use in future research.

Who will have access to the donated samples?

The only people having access to the tissue will be research teams, including clinical and laboratory staff working on this project.

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How will this study benefit me?

This study is unlikely to be of immediate personal benefit to you. We hope that this study will enable us to develop better diagnosis and treatment strategies for the future management of kidney cancer, the incidence of which is increasing every year.

Will my GP/Family doctor be informed?

With your permission, your GP will be informed of your participation in this study. However, your normal care pathway will not be affected, and if for any reason you would not like your GP to know, this will be respected.

How will we use information about you?

We will need to use information from your medical records for this research project.

This information will include your
- NHS number and local hospital number
- Name
- Date of birth
- Contact details

People will use this information to do the research or to check your records to make sure that the research is being done properly. This includes researchers at the Royal Free London.

Researchers who do not need to know who you are, for example researchers at Pear Bio, will not be able to see your name or contact details. Your data will be identified with a code instead.

We will keep all information about you safe and secure.

Some of your information may be sent to outside the UK. They must follow our rules about keeping your information safe.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. This will not affect your current or future clinical care. If your tissue or blood samples have not yet been used, then the samples will be destroyed using the usual protocol for

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human materials.

If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records, your hospital and your GP. If you do not want this to happen, tell us and we will stop.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to **Steve O'Connell** steven@pearbio.com, or
- by ringing us on 07841247505

Who is organising the research?

The study is being conducted at the Specialist Centre for Kidney Cancer at the Royal Free Hospital and at Ourotech Limited (trading as Pear Bio). Miss Maxine Tran is the Consultant in charge of the study at the Royal Free London.

Who is the sponsor of the research?

Ourotech Limited (trading as Pear Bio) is the sponsor of this study. Pear Bio is a London-based diagnostics company that creates organ-on-a-chip and computer vision tools to study cancer. Pear Bio develops precision medicine lab tests to monitor tumour sample response to therapy. These tests may help doctors select effective therapy for individual patients in the future.

What will happen to the results of this study?

The results will be published in a scientific journal and presented at scientific conferences. No details of individual patients will be presented. A copy of the presentations or publications will be available to you on your request.

Who has reviewed this study?

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This study has been approved by the National Research Ethics Service Committee (REC ref: 22/YH/0068)

Who do I contact if I have any questions or if there's a problem and I'd like to complain?

If you have any questions, a problem or a complaint, please consult your consultant, or contact us below. You may also find it useful to contact cancer BACUP, an independent patient advisory group (Freephone 0800181199).

Research team contact:

Maxine Tran
Email: rf-tr.kidneycancerresearch@nhs.net

Hannah Warren
Email: hannah.warren2@nhs.net
Tel: 07708914622

Thank you for your time spent reading this information sheet and considering this study.