

# Understanding the usefulness of the PEAR-BIO platform in patients with kidney cancer

<b>Submission date</b> 19/08/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 14/10/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/11/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Kidney cancer represents a major unmet healthcare need. There is a range of treatments that are available for patients with kidney cancer, although it can be difficult to know which treatment is best for different patients.

We have developed a novel platform that uses a sample of a patient's tumour to directly test different drugs and try and predict which drug(s) might work best for different patients. The first step in this process is to assess the correct dose of different treatments on our platform.

This study aims to use tissue on our platform from patients with kidney cancer who are having surgery to assess the correct dose of each of the drugs for use in our system. Our secondary objectives are around checking to see how these correlate with existing biomarkers.

### Who can participate?

Adult patients with operable kidney cancer who are undergoing surgery, and are able to donate 40 ml of blood

### What does the study involve?

Patients provide informed consent and have surgery as normal, as well as providing a 40 ml blood sample.

### What are the possible benefits and risks of participating?

There are no direct benefits from participation, other than helping to develop a test that might help predict treatment response in the future, and the general increase in scientific knowledge. There should be no additional risks. Patients will have surgery as planned, and the donation of 40 ml of blood should pose no additional risk.

### Where is the study run from?

The Royal Free Hospital NHS Foundation Trust (United Kingdom)

### When is the study starting and how long is it expected to run for?

February 2022 to March 2023

Who is funding the study?  
Pear Bio (United Kingdom)

Who is the main contact?  
1. Prof. Maxine Tran (Principal investigator) (United Kingdom)  
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2. Dr. Matthew Williams (Medical Director) (United Kingdom)  
Matthew@pearbio.Com

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Maxine Tran

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### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil Known

### Integrated Research Application System (IRAS)

312529

### ClinicalTrials.gov (NCT)

Nil Known

### Protocol serial number

IRAS 312529, CPMS 52231

## Study information

Scientific Title

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

## Acronym

PEAR-TREE

## Study objectives

We have developed a new AI-enabled, tissue-sample-based platform to provide a functional precision medicine approach. This study will apply the platform to renal cancer, with a particular focus on immunotherapy drugs.

Our main aim is to establish the correct dose of FDA-approved therapies in renal cell carcinoma in our model. Secondary objectives include understanding the correlation between biomarkers and response in our system.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 03/03/2022, Yorkshire & The Humber - Bradford Leeds REC (NHSBT Newcastle Blood Donor Centre, Holland Drive, Newcastle Upon Tyne, Tyne and Wear, NE2 4NQ, United Kingdom; +44 (0)207 104 8083; bradfordleeds.rec@hra.nhs.uk), ref: 22/YH/0068

## Study design

Observational single-centre non-randomized trial

## Primary study design

Observational

## Study type(s)

Other

## Health condition(s) or problem(s) studied

Patients undergoing surgery for renal cell carcinoma

## Interventions

Patients will undergo surgery as standard. We will use tissue from surgery, combined with a blood sample, and take these to the lab.

The tissue will be split into multiple samples, and then tested on our platform. We grow the cells in multiple different wells, using one as a control, and test various drugs and immunotherapy agents in the other wells. We then image the wells on days 0, 1, 2, 3 and 4 and report the extent of cell viability, migration and activation and invasion of immune cells.

Drugs being tested alone or in combination include:

1. Ipilimumab + nivolumab
2. Axitinib + pembrolizumab
3. Cabozantinib + nivolumab
4. Lenvatinib + pembrolizumab
5. Pazopanib

6. Sunitinib
7. Sorafenib
8. Everolimus
9. Sapanisertib

**Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Ipilimumab, nivolumab, axitinib, pembrolizumab, cabozantinib, lenvatinib, pazopanib, sunitinib, sorafenib, everolimus, sapanisertib

**Primary outcome(s)**

Assessment of the functional dose of FDA-approved drugs for renal cell carcinoma and confirmation of mechanism of action, both intra- and inter-patient variation, measured using cell alive/dead ratio in an ex-vivo assay at days 0 - 5 time points

**Key secondary outcome(s)**

Assess the correlation of biomarkers to ex vivo tumour response via multi-omics analyses. Biomarkers include gene and protein expression (using RNASeq and ELISA) measured against ex-vivo response, which includes measures of cell alive/dead ratios, invasion and migration, and immune cell infiltration at days 0 - 5 timepoints:

1. The relationship between biomarkers and ex vivo response
2. Ordinal regression correlating biomarker response against ex vivo treatment sensitivity/resistance

**Completion date**

31/03/2023

**Eligibility****Key inclusion criteria**

1. Aged 18 years old and over
2. Patients with operable kidney cancer
3. Able to give informed consent
4. Able to give 40 ml of blood and surgical sample yields  $\geq 0.4$  g of cancerous tissue

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Inoperable or metastatic kidney cancer
2. Pre-operative haemoglobin levels below 120g/l
3. Patients who have already commenced chemotherapy, targeted therapy, immunotherapy or radiotherapy
4. Recurrence of cancer from any other site than the kidney
5. Any other disease or finding that renders the patient at high risk of treatment complications or interferes with obtaining informed consent

**Date of first enrolment**

01/10/2022

**Date of final enrolment**

31/03/2023

**Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Royal Free London NHS Foundation Trust**

Royal Free Hospital

Pond Street

London

United Kingdom

NW3 2QG

**Sponsor information**

**Organisation**

Ourotech Limited (trading as Pear Bio)

**Funder(s)**

**Funder type**

Industry

## Funder Name

Ourotech Limited (trading as Pear Bio)

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available because these data are from confocal microscopy on our platform, and as such are not interpretable by external users

### IPD sharing plan summary

Not expected to be made available

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	version 1.1	03/03/2022	28/09/2022	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes