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

Submission date
19/08/2022

Recruitment status
No longer recruiting

Registration date
14/10/2022

Overall study status
Completed

Last Edited
01/11/2022

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English Summary

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

Study website
https://www.pearbio.com/clinical-trials

Contact information

Type(s)
Principal Investigator

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Prof Maxine Tran

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Additional identifiers

EudraCT/CTIS number
Nil Known

IRAS number
312529

ClinicalTrials.gov number
Nil Known

Secondary identifying numbers
IRAS 312529, CPMS 52231

Study information

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

Acronym
PEAR-TREE

Study hypothesis
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

Secondary study design
Case series

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See trial outputs table

Condition
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 measure
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

Secondary outcome measures
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

Overall study start date
01/02/2022

Overall study end date
31/03/2023

Eligibility

Participant 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 >= 0.4 g of cancerous tissue

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Participant 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

Recruitment start date
01/10/2022

Recruitment end date
31/03/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Free London NHS Foundation Trust
Royal Free Hospital
Pond Street

London
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Sponsor information

Organisation
Ourotech Limited (trading as Pear Bio)

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Ourotech Limited (trading as Pear Bio)

Results and Publications

Publication and dissemination plan
1. Planned publication in a peer-reviewed journal
2. Conferences
3. Company website

Intention to publish date
01/12/2023

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?
Participant information sheet	version 1.1	03/03/2022	28/09/2022	No	Yes
HRA research summary			28/06/2023	No	No