**Patient Information Sheet**

**REMAP: Evaluation of treatment response and resistance in metastatic renal cell cancer using integrated 18F-Fluorodeoxyglucose (18F-FDG) positron emission tomography/magnetic resonance imaging (PET/MRI)**

**Investigators**

Principle Investigator: Professor Vicky Goh (Radiology)

Co-Investigator: Professor Gary Cook (PET Centre)

**Introduction:**

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

1. **What is the purpose of this study?**

Our aim is to find out if a new type of imaging scan (PET/MRI) combining two different imaging techniques (PET &MRI) into one examination can improve our detection of whether your drug treatment is working (response) or not (poor response/relapse). PET/MRI will allow us not just to measure size but also how your kidney cancer is functioning (by its sugar uptake & blood supply). We hope this additional information will be able to tell us how your treatment is working at an earlier time point, and in the future allow doctors to change your treatment earlier, if we can show this test is better than CT at showing poor response or relapse.

**2. Why have I been invited to take part?**

You have been invited to take part in this IMAGING study because you are undergoing drug treatment for your kidney cancer.

**3. Do I have to take part?**

It is up to you whether you would like to take part or not. If you decide to take part, you will be given these information sheets to keep and 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 treatments or standard of care that you will receive.

**4. What will happen if I take part?**

You will be invited to have 3 PET/MRI scans in addition to your standard imaging scan (CT, computed tomography): one before starting drug treatment, one at approximately 12 weeks into treatment and then at 24 weeks into treatment.

A leaflet will be given to you explaining how PET/MRI scans are performed and what to expect when you come for a scan.

We may also request access to pathology samples from biopsies or surgery you may have had previously relevant to your diagnosis of kidney cancer at Guy’s and St Thomas’ hospital. This is to explore whether there is a relationship to be drawn between the scan results and the pathology specimen findings.

**5. What are the scans and what do they involve?**

A PET/MRI scanner performs both the PET and MRI scan at the same time.

As part of the scan, you will be asked to fast for 6 hours before the scan appointment. You will have a cannula placed in an arm vein and a small amount of radioactive sugar (18F-fluorodeoxyglucose) injected. You then lie still for approximately 60 minutes, to allow this sugar to be taken up by your cancer before your scan. During the scan a non-radioactive dye (gadolinium contrast agent) that will show up the blood supply to the cancer will also be given though the cannula.

PET Scan: FDG PET scans measures sugar metabolism which is different between active and inactive cancer; this may be able to detect changes due to treatment before the tumour shrinks.

MRI scan: MRI uses a strong magnetic field to obtain high quality images and following contrast injection (gadolinium) can show up the blood supply to your cancer.

The scanner is noisy, and people who suffer from claustrophobia may feel uncomfortable. Please let us know if you suffer from claustrophobia. You will be asked to complete a standard safety questionnaire as a routine precaution to check that you do not have any metal implants or metal fragments in your body. We also will need to know about tattoos as some of these can contain lead-based inks.

Following the PET/MRI scan you will be able to eat and drink as normal. Refreshments are available in the PET Centre.

Scheduling your scan appointments: We will do our best to arrange your CT scan and research PET/MRI on the same day. If we are unable to schedule both tests on the same day we will attempt to arrange the PET/MRI in the morning so that you will be finished earlier in the day in time for lunch.

**5. What are the alternatives?**

Entry into this research study is entirely voluntary and will not affect your treatment if you decide not to take part.

**6. What if I do not want to take part?**

We would respect your decision. You will receive the usual investigations and treatment that is appropriate for your condition.

**7. What are the side effects and possible disadvantages of taking part?**

The MRI and PET imaging tests are safe and are in clinical use.

**Gadolinium:** Has been in use for over 15 years worldwide, with very few serious complications reported. Rare side effects include mild headache, light headedness, itching skin, breathing difficulty, nausea, vomiting and local pain. < 1 in 1000 patients may experience a hypersensitivity or allergic reaction.

**Radioactive tracer:** A small amount of radiation is received as part of the PET scan. This is equivalent to approximately 3 years of the background radiation that we all experience.

The radiation disappears (decays) very quickly, and does not affect the normal body processes. However, there are standard recommendations not to have close contact with pregnant women, babies and young children for a few hours after the scan.

Please note any radiation carries a very small risk of developing an additional cancer in later life. The additional risk from taking part in this research is 1 in 797.

Unexpected Findings: The PET/MRI scans will be read by specialists and it is possible that the scan may reveal unexpected findings which may or may not relate directly to the kidney cancer but require treatment or further tests for clarification. If this should happen the results will be communicated to the clinical team responsible for your care with recommendations on next steps.

**10. What are the possible benefits of taking part?**

The PET/MRI will provide information on how your cancer is responding to treatment. Apart from that there is no immediate direct benefit to you. However the information we will get from this study will help us to improve future patient care by improving how we assess treatment and allow patients who are not responding to have the option to change treatment.

**11. What happens to the information?**

If you decide to participate in the study, your actual identity will remain confidential. Only the staff directly involved in the study will have access to research data. The data will be stored in a secure room in the hospital.

**12. Who is taking part?**

 This study is being conducted at Guy’s and St Thomas’ NHS Trust.

**13. What if something goes wrong?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the Guy’s and St Thomas’ Patients Advice and Liaison Service (PALS) on 020 7188 8801, pals@gstt.nhs.uk. The PALS team are based in the main entrance on the ground floor at St Thomas’ Hospital and on the ground floor at Guy’s Hospital in the Tower Wing.

In the event that something does go wrong and you are harmed during the research you may have grounds for legal action for compensation against Guy’s and St Thomas’ NHS Foundation Trust and/or King’s College London but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

**14. What happens at the end of the research study?**

At the end of the study, we will review all the imaging, clinical and pathological data and the results will be presented at meetings and published in a medical journal. At no time will it be possible for you to be identified by name.

**15. What if I have more questions or do not understand something?**

Please ask any of the research team, the doctor or nurses who are caring for you in the hospital, or your GP.

**16. What happens now if I decide to take part?**

You will be asked to sign a consent form before taking part. You will be given a copy of both the consent form and information sheet to keep. Your GP may be informed that you are taking part in the study, if you so wish. We will then perform the imaging test before you are treated.

**17. What happens if I change my mind during the research study?**

If you decide that you no longer want to take part in the study then you can withdraw from it at any time. This will not compromise your hospital care in any way. Any data obtained up to the point of your withdrawal will be kept in the securely stored database.

**18. Who is organizing this research?**

This research is being organized by the PET Centre and Department of Radiology at Guy’s and St Thomas’ NHS Trust and King’s College London and funded by Cancer Research UK.

**19. What if I have any concerns or if there is problem?**

If you have any concerns or other questions about this study or any problems please contact us:

**Research team:** 0207 188 5538 or 0207 188 188 extn 51251  **Clinical research fellow:** Dr Christian Kelly-Morland
Email: Christian.kelly-morland@kcl.ac.uk

**Clinical research nurse:** Mr Adrian Green
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**Trials co-ordinator:** Ms Dorothee Boisfer

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**20. Who has reviewed this study?**

The study has been reviewed and approved by the London – South East Research Ethics Committee, 16/LO/1499.

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