

# Assessing response to treatment using imaging with PET/MRI in advanced renal cancer

<b>Submission date</b> 02/11/2016	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 16/11/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 13/07/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-pet-mri-scans-for-people-with-kidney-cancer-that-has-spread-remap>

## Contact information

### Type(s)

Scientific

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## Additional identifiers

### Protocol serial number

31962

## Study information

### Scientific Title

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

### Acronym

REMAP

### Study objectives

PET/MRI improves response classification compared to routine CT imaging in metastatic renal cell carcinoma.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Southeast London Research Ethics Committee, 10/10/2016, ref: 16/LO/1499

### Study design

Randomised; Interventional; Design type: Diagnosis, Process of Care, Imaging

### Primary study design

Interventional

### Study type(s)

Diagnostic

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

Renal cell carcinoma

### Interventions

Participants with metastatic renal cell cancer will undergo FDG PET/MRI scans at baseline, 12 and 24 weeks following the start of their standard treatment and results compared to the routine clinical CT scans at these time-points. Each PET/MRI will take approximately one hour. The imaging intervention is over 24 weeks and the imaging follow up period extends to the 36 week clinical CT scan. Subsequent consensus panel assessment of clinical and all imaging data up to 36-weeks will confirm disease status.

### **Intervention Type**

Other

### **Primary outcome(s)**

disease response or non-response measured by PET/MRI and CT at 12 and 24 weeks and clinical examination and CT at 36 weeks.

### **Key secondary outcome(s)**

Time to progression will be measured by clinical examination and CT at standard three to six monthly follow up clinic visits.

### **Completion date**

01/02/2023

## **Eligibility**

### **Key inclusion criteria**

1. Adult patients (male or female > 18 years old) with metastatic renal cell carcinoma
2. Metastases with  $\geq 1$  measurable sites,  $\geq 2$ cm, planned for targeted therapy
3. ECOG performance status 0-2

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. Contraindications to contrast-enhanced MRI or CT or FDG PET including renal impairment eGFR <50
2. Estimated prognosis < 12 weeks
3. ECOG performance status > 2
4. Previous radiotherapy

**Date of first enrolment**

01/12/2016

**Date of final enrolment**

31/07/2022

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre****King's College London and Guy's and St Thomas' PET Centre**

Level 1, Lambeth wing

St. Thomas' Hospital

Guy's and St. Thomas' NHS foundation Trust

Westminster Bridge Road

London

United Kingdom

SE1 7EH

**Study participating centre****Mount Vernon Cancer Centre**

East and North Hertfordshire NHS trust

Mount Vernon Hospital

Rickmansworth Road

Northwood

United Kingdom

HA6 2RN

## Sponsor information

**Organisation**

King's College London

**ROR**

<https://ror.org/0220mzb33>

## Funder(s)

**Funder type**

Charity

**Funder Name**

Cancer Research UK

**Alternative Name(s)**

CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Other non-profit organizations

**Location**

United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are/will be available upon request from Professor Vicky Goh (vicky.goh@kl.ac.uk)

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	02/06/2017		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	version V1.1	29/06/2016	16/11/2016	No	Yes