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

Submission date	Recruitment status	[X] Prospectively registered	
02/11/2016  Registration date	No longer recruiting  Overall study status	[X] Protocol	
		Statistical analysis plan	
16/11/2016  Last Edited	Completed  Condition category	Results	
		Individual participant data	
13/07/2022	Cancer	<ul><li>Record updated in last year</li></ul>	

#### Plain English summary of protocol

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

# Contact information

# Type(s)

Scientific

#### Contact name

Prof Vicky Goh

#### **ORCID ID**

http://orcid.org/0000-0002-2321-8091

#### Contact details

Division of Imaging Sciences & Biomedical Engineering, King's College London Level 1, Lambeth wing St. Thomas' Hospital Westminster Bridge Road London United Kingdom SE1 7EH +44 (0)207 188 5538 vicky.goh@kcl.ac.uk

#### Type(s)

Scientific

#### Contact name

**Prof Gary Cook** 

#### Contact details

Division of Imaging Sciences & Biomedical Engineering, King's College London Level 1, Lambeth wing St. Thomas' Hospital Westminster Bridge Road London United Kingdom SE1 7EH +44 (0)207 188 5538 gary.cook@kcl.ac.uk

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers 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

# Secondary study design

Randomised controlled trial

#### Study setting(s)

Hospital

## Study type(s)

Diagnostic

## Participant information sheet

See additional files

## 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 measure

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

## Secondary outcome measures

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

# Overall study start date

16/05/2015

# 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 ≥1 measurable sites, ≥2cm, planned for targeted therapy
- 3. ECOG performance status 0-2

# Participant type(s)

Patient

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

#### Target number of participants

Planned Sample Size: 38; UK Sample Size: 38

#### 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

England

**United Kingdom** 

#### 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

#### Sponsor details

Guy's Campus King's College London London England United Kingdom SE1 4UL

#### Sponsor type

University/education

#### **ROR**

https://ror.org/0220mzb33

# Funder(s)

# Funder type

Charity

#### **Funder Name**

Cancer Research UK

#### Alternative Name(s)

CR\_UK, Cancer Research UK - London, CRUK

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

Other non-profit organizations

#### Location

**United Kingdom** 

# **Results and Publications**

## Publication and dissemination plan

Preliminary/interim results of the study will be disseminated by conference presentation during the trial and the final results submitted for publication in relevant peer reviewed journals where applicable within a year of the trial end date.

# Intention to publish date

01/02/2024

# 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?
Participant information sheet	version V1.1	29/06/2016	16/11/2016	No	Yes
<u>Protocol article</u>	protocol	02/06/2017		Yes	No
HRA research summary			28/06/2023	No	No