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

	[X] Prospectively registered		
No longer recruiting	[X] Protocol		
Overall study status	Statistical analysis plan		
Completed	Results		
Condition category	Individual participant data		
Cancer	Record updated in last year		
	Completed Condition category		

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

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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 ≥ 1 measurable sites, ≥ 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

Αll

Kev 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?
<u>Protocol article</u>	protocol	02/06/2017		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V1.1	29/06/2016	16/11/2016	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes