ISRCTN12114913 https://doi.org/10.1186/ISRCTN12114913

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

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

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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Prof Gary Cook

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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
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England
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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
Protocol article	protocol	02/06/2017		Yes	No
HRA research summary			28/06/2023	No	No