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Can a nuclear medicine scan (MIBI) detect whether a mass in the kidney is cancer?

Submission date 15/12/2020	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/01/2021	**Overall study status** Ongoing	
Last Edited 08/04/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims

The diagnosis of kidney tumours is increasing, and results in an increasing amount of kidney surgery being performed. Not all kidney tumours are cancer, and up to 3 in 10 can be benign. Currently, the only way to tell whether a tumour is benign or cancer is to have a biopsy. However, this also has risks such as pain, bleeding and patients worry about potential 'spillage' of the tumour from the biopsy. Many hospitals do not offer renal tumour biopsy.

New studies from the USA and Sweden have shown that a type of nuclear medicine scan called 'Sestamibi' (MIBI) can distinguish renal cancer from benign tumours. MIBI scans are currently being used in the NHS for other diseases such as parathyroid and heart muscle imaging and are known to be very safe, painless and widely available.

This study will investigate if MIBI can be used for patients diagnosed with renal masses in the UK.

Adult patients diagnosed with a renal mass larger than 2cm will be invited to participate by having a MIBI scan prior to their scheduled biopsy or surgery. For this feasibility study, it is planned to recruit 30 patients. The second part of this study is to explore the acceptability of MIBI scans by interviewing and surveying perception amongst patients and clinicians (aim for 20 semi-structured interviews).

Who can participate?

Adults aged 18 - 95 years diagnosed with a renal mass larger than 2cm and are either scheduled to have this biopsied, or have previously had this biopsied and are on active surveillance.

What does the study involve?

Taking part involves agreeing to attend the hospitals' nuclear medicine department for a MIBI scan, in addition to your routine appointments and scans. This would mean not having anything to eat or drink for 4 hours before the appointment. You will have an injection of a small amount of radio-labelled tracer into a vein in your arm, and then will have SPECT/CT scan about 75 minutes after this. It is likely that this additional visit will take between 2-3 hours.

You will also be asked to complete a short questionnaire on your quality of life and for feedback of your experience at the appointment, and via telephone at 24 hours and 2 weeks.

You will also be asked to consent for access to your histology, blood and imaging results and follow up. You will be assigned a study ID and your clinical details linked to this ID. The chief

investigator and your direct clinical care team will have access to this data, no identifiable data will be shared with researchers.
You will be asked to donate additional research blood samples and tissue samples if you have not yet had a biopsy of your kidney tumour (this will be optional).
You may also be asked if you would like to participate in an audio-recorded interview on the perceptions of the scan in the diagnostic pathway of kidney tumours. The interviews will be after the scan, and can be held in person, over the phone, or on an on-line platform such as Zoom. The interviews are likely to last between 10-20 minutes. The recordings will be assigned a code (pseudo-anonymised), transcribed and analysed using specific qualitative data analysis software (for example NVivo). Direct quotations may be used, but you will not be identified in any publications or reports.

What are the possible benefits and risks of participating?
We do not anticipate any benefits to you because of your involvement in this research but the information we get from this study may help improve the treatment of people diagnosed with kidney tumours. Taking part in this study means an additional visit and nuclear medicine scan, which means inconvenience in terms of travelling time and time spent having the investigation. This is recognised and participants are offered £60 in vouchers or cash from the Hospital's cashier office to compensate for this. The scan also involves exposure to a small radiation dose. The study has been reviewed by a medical physics expert, clinical radiation expert and the REC which have considered the risk to be very small. Ionising radiation can cause cancer which manifests itself after many years or decades. The risk of developing cancer as a consequence of taking part in this study is estimated as 0.07% (1 in 1429). For comparison, the natural lifetime cancer incidence in the general population is about 50% (1 in 2). The injection into the vein may cause pain and bruising, though we anticipate this to be temporary. MIBI scans have been in routine use in the NHS to investigate other conditions including the parathyroid and heart muscle, there have been no reports of any significant adverse events. Participation in this study is therefore considered low risk.

Where is the study run from?
The Royal Free Hospital (UK)

When is the study starting and how long is it expected to run for?
November 2020 to March 2029

Who is funding the study?
Royal College of Surgeons of England (UK)

Who is the main contact?
Dr Maxine Tran, m.tran@ucl.ac.uk

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-a-new-scan-to-improve-the-diagnosis-of-kidney-cancer

Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
282927

Central Portfolio Management System (CPMS)
47108

Study information

Scientific Title
A feasibility study to investigate the acceptability of 99m Tc SestaMIBI SPECT/CT for kidney mass characterisation

Acronym
MIBI for kidney

Study objectives
The use of 99mTc Sestamibi SPECT/CT improves the diagnostic pathway of renal tumours.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 26/11/2020, Yorkshire and the Humber - Sheffield Research Ethics Committee (Barlow House, 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; +44 (0)207 104 8237; sheffield.rec@hra.nhs.uk), ref: 20/YH/0279

Primary study design
Observational

Study design
Cohort study

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Characterisation of kidney masses to identify cancer

Interventions
After consent and eligibility is confirmed, participants will attend the Royal Free Hospital for the 99mTc Sestamibi SPECT/CT scan. This is likely to take place within 2 weeks of providing consent. The nuclear medicine consultant or their delegate will confirm consent, answer any further questions participants may have and administer the i.v. injection. This will be followed 75 min later by SPECT/CT of the abdomen from the dome of the liver to the upper pelvis. Two telephone based assessments will occure at 24 hours and 2 weeks post the scan to record side effects and patient experience. Participants will also be asked to fill in questionnaires over this period. Participants will then be followed up for 5 years.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
99m Tc SestaMIBI SPECT/CT

Primary outcome(s)
Sensitivity and specificity of the 99mTc-sestamibi SPECT/CT scan to detect cancer reported by the nuclear medicine consultant (results will be matched with the histological tissue diagnosis, either by conventional tumour biopsy or surgery [the reference standard]) at a single timepoint

Key secondary outcome(s)
Acceptability of 99mTc Sestamibi SPECT/CT scans in the diagnostic pathway of renal masses measured the Quality of Life questionnaire (EQ5DL) will given at screening (pre-treatment), as part of the first telephone assessment (day 15 + 2 days) and the second telephone assessment (day 28 + 14 days)

Completion date
30/03/2029

Eligibility

Key inclusion criteria
1. Adult patients >18 years of age and less than 95 years
2. Renal tumour >2 cm identified on cross sectional imaging (CT or MRI)
3. Patients undergoing tumour biopsy, surgery or who have previously had a biopsy and are on active surveillance programmes
4. Capacity to provide informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
50

Key exclusion criteria
1. Females who are pregnant, planning pregnancy or breastfeeding
2. Concurrent and/or recent involvement in other research that is likely to interfere with the intervention within 3 months of study enrolment
3. Multiple comorbidities which would make trial participation difficult (e.g. burden of an additional hospital visit)
4. Allergy to 99m Tc-sestamibi

Date of first enrolment
01/04/2021

Date of final enrolment
30/03/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Royal Free Hospital
Royal Free London NHS Foundation Trust
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre

Royal Devon and Exeter Hospital
Royal Devon University Healthcare NHS Foundation Trust
Barrack Road
Exeter
United Kingdom
EX2 5DW

Study participating centre
Worthing Hospital
University Hospitals Sussex NHS Foundation Trust
Lyndhurst Road
Worthing
United Kingdom
BN11 2DH

Study participating centre
Leeds General Infirmary
United Leeds Teaching Hospitals NHS Trust
Great George Street
Leeds
United Kingdom
LS1 3EX

Study participating centre
Addenbrookes Hospital
Cambridge University Hospitals NHS Foundation Trust
Cambridge Biomedical Campus
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Guy's and St Thomas' Hospitals
Trust Offices
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
University College London

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Research organisation

Funder Name
Royal College of Surgeons of England

Alternative Name(s)
RCS England, RCS ENG, The Royal College of Surgeons of England, RCS

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Available on request, Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No