

# Can a nuclear medicine scan (MIBI-kidney) tell us if a mass in the kidney is cancer?

<b>Submission date</b> 28/04/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 05/05/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 25/01/2023	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

In the UK, over 13,000 people are diagnosed with kidney tumours every year. Most are detected by chance on scans performed for other purposes. Standard treatment is surgical removal of the tumour together with part or the whole kidney, which carries serious risks and reduces overall kidney function. However, not all kidney tumours are cancers and up to 3 in 10 are benign (most are oncocytomas) which do not cause harm and do not need removal. Currently, to tell if a tumour is benign or cancer requires having it surgically removed or having a biopsy. However, a biopsy is still an invasive procedure and most patients experience pain, and bruising, and must stop blood thinning tablets beforehand to reduce the risk of bleeding. Some patients and doctors also worry about 'cancer spillage' from disrupting the tumour during a biopsy.

New studies from the USA, Sweden and China show that a type of nuclear medicine scan called 'sestamibi' (MIBI-kidney) can distinguish cancer from benign kidney tumours. MIBI-kidney scans use very small doses of radio-active tracer and are safe, non-invasive and painless. They are currently used in the NHS for other indications, such as parathyroid and heart scans, and we have successfully performed a small study for patients with kidney tumours in our hospital.

This feasibility study will find out if MIBI scans can be used for patients with kidney tumours, and will also assess patient and clinician acceptability. The results will help design a larger multi-centre study to fully test the effectiveness of these scans in the NHS.

### Who can participate?

We will invite people diagnosed with kidney tumours who are planning to have either a biopsy or surgery, to take part in this study and consent to have a MIBI scan.

### What does the study involve?

Taking part involves agreeing to attend the nuclear medicine department for a MIBI-kidney scan, in addition to other routine appointments. The visit involves an injection of the study tracer 75 minutes before the study scan. The visit will take 2-3 hours in total. Participants will be asked to complete questionnaires on their quality of life before the scan and 24-72 hours afterwards.

Additionally, participants will be invited to participate in an audio-recorded interview on their perceptions of the scan, and complete a survey on decision making with respect to health care choices.

What are the possible benefits and risks of participating?

We cannot promise the study will help you but the information we get from this study may help improve the treatment of people diagnosed with kidney tumours in future.

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?

University College London (UK)

When is the study starting and how long is it expected to run for?

November 2020 to August 2024

Who is funding the study?

The National Institute for Health and Care Research (NIHR) (UK) is funding the study. The researchers running the study have also received support from The Urology Foundation, Pan London Cancer Alliance, Royal College of Surgeons of England and Royal Free Hospital Charity, St Peter's Trust for this work.

Who is the main contact?

Hannah Warren, Clinical Research Fellow  
rf-tr.kidneycancerresearch@nhs.net

## Contact information

### Type(s)

Principal investigator

### Contact name

Miss Maxine Tran

### ORCID ID

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### Contact details

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

282927

### **Protocol serial number**

IRAS 282927

## **Study information**

### **Scientific Title**

A MULTI-centre feasibility study to assess the use of 99m Tc-SestaMIBI SPECT/CT in the diagnosis of kidney tumours (MULTI-MIBI study)

### **Acronym**

MULTI-MIBI

### **Study objectives**

It is feasible to recruit to a multi-centre study including MIBI-kidney prior to histological diagnosis

### **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

### **Study design**

Single-gate cross sectional diagnostic test accuracy study

### **Primary study design**

Intentional

## Study type(s)

Diagnostic

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

Kidney cancer

## Interventions

After consent, and eligibility is confirmed, all participants will attend for the study 99mTc Sestamibi SPECT/CT scan (MIBI-kidney). This is likely to take place within 2 weeks of providing consent. The nuclear medicine consultant or their delegate will administer the i.v. radiotracer injection and after 75 min, perform SPECT/CT of the abdomen from the dome of the liver to the upper pelvis. A telephone or email-based assessment at 24-72 hours will record any side effects, patient experience and quality of life assessment. After the scan, participants may be invited to an optional video-interview to explore their experience, and to fill in a study questionnaire. These study activities are expected to be complete within 6 months of enrollment. Participants will consent to clinical follow for up to 5 years.

## Intervention Type

Device

## Phase

Not Applicable

## Drug/device/biological/vaccine name(s)

99m Tc SestaMIBI

## Primary outcome(s)

1. Recruitment rate will be recorded as the number of eligible participants who consent to participate in the study after 15 months of recruitment.
2. Attrition rate will be recorded as the number of participants that enroll in the study but do not complete activities outlined in the protocol.

## Key secondary outcome(s)

1. Qualitative data will be obtained from semi-structured video-interviews after the intervention to assess barriers and enablers of trial set-up, recruitment and delivery.
2. Exploratory health economic analysis will be informed by quality-of-life assessment at baseline and 24 hours after MIBI-kidney using the validated EQ-5D-5L instrument.
3. Costs incurred by MIBI-kidney, and other stages of the diagnostic pathway will be collected from NHS reference costs at the end of the study to inform design of a future health economic analysis

## Completion date

31/08/2024

## Eligibility

### Key inclusion criteria

1. Age >18 years, and <95 years of age
2. Any gender
3. cT1 renal tumour >2cm identified on cross sectional imaging (CT or MRI) of unknown

histological diagnosis

4. Patients undergoing tumour biopsy or surgery as part of routine care

5. Willing and able to provide informed consent.

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

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Upper age limit**

95 years

### **Sex**

All

### **Total final enrolment**

150

### **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  $^{99m}\text{Tc}$  Sestamibi

### **Date of first enrolment**

01/10/2022

### **Date of final enrolment**

28/02/2024

## **Locations**

### **Countries of recruitment**

United Kingdom

England

### **Study participating centre**

Royal Free London NHS Foundation Trust

Royal Free Hospital

Pond Street  
London  
United Kingdom  
NW3 2QG

**Study participating centre**

**Guy's Hospital**  
Great Maze Pond  
London  
United Kingdom  
SE1 9RT

**Study participating centre**

**Royal Devon & Exeter Foundation Hospital**  
Barrack Road  
Exeter  
United Kingdom  
EX2 5DW

**Study participating centre**

**Leeds Teaching Hospitals NHS Trust**  
St. James's University Hospital  
Beckett Street  
Leeds  
United Kingdom  
LS9 7TF

## **Sponsor information**

**Organisation**

University College London

**ROR**

<https://ror.org/02jx3x895>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

National Institute for Health Research

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Funder Name**

The Urology Foundation

**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

**Funder Name**

St Peter's Trust for Kidney Bladder and Prostate Research

**Alternative Name(s)**

St Peter's Trust for Kidney, Bladder and Prostate Research, St Peter's Trust for Kidney Bladder & Prostate Research, SPT

**Funding Body Type**

Private sector organisation

## Funding Body Subtype

Other non-profit organizations

## Location

United Kingdom

## Funder Name

Pan London Cancer Alliance

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication

## IPD sharing plan summary

Published as a supplement to the results publication

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>		24/01/2023	25/01/2023	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No