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

Submission date
28/04/2022

Recruitment status
No longer recruiting

Registration date
05/05/2022

Overall study status
Completed

Last Edited
25/01/2023

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
282927

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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 measure
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.

Secondary outcome measures
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

Overall study start date
26/11/2020

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
95 Years

Sex
Both

Target number of participants
50 + 100 to complete discrete choice experiment survey

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 99mTc Sestamibi

Date of first enrolment
01/10/2022

Date of final enrolment
28/02/2024

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor details
UCLH/UCL joint research office
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London
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United Kingdom
NW3 2QG
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uclh.randd@nhs.net

Sponsor type
University/education

Website
http://www.ucl.ac.uk/

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

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

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

Publication and dissemination plan
Planned publications of the protocol and study results in high-impact peer-reviewed journals.

Intention to publish date
31/08/2025

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?
Protocol article		24/01/2023	25/01/2023	Yes	No
HRA research summary			28/06/2023	No	No