

# What are the benefits and drawbacks to having a kidney tumour biopsy?

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<b>Registration date</b> 16/12/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 22/09/2021	<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

Kidney tumours are increasingly detected in patients having investigations for unrelated symptoms. Currently, it is not possible to tell whether a tumour is not cancerous (benign) or is cancer by a scan, blood or urine test. Most patients diagnosed with a kidney tumour are offered surgery, but this carries serious risks. These include a 1 in 20 risk of a major complication requiring intervention such as injury to the bowel, liver or spleen and a 1 in 200 risk of death. A sample of tissue (biopsy) can usually tell whether a kidney tumour is benign or cancer. Some hospitals offer biopsies for small kidney tumours and it can change the way in which a patient may want to have their tumour treated. Instead of surgery, patients with benign tumours often choose to have monitoring or alternative treatments such as freezing the tumour which has fewer risks. Most side effects of biopsies (discomfort, bruising, and blood in the urine) get better without treatment. Nearly 6 in 10 kidney tumours are benign or are low grade (59%), meaning that they are unlikely to cause harm. This means that over half of patients can potentially avoid surgery if they have a biopsy.

Currently, access to biopsies is not equal across the UK. This study aims to find out what the barriers are and what action is required to offer a tumour biopsy service to all patients to help guide treatment decision and improve outcomes.

### Who can participate?

Healthcare professionals involved in kidney tumour biopsy and patients who have or have had a kidney tumour (small renal mass)

### What does the study involve?

We will interview doctors, commissioners, and patients to explore current service and viewpoints on the role of biopsy in the diagnosis of kidney lumps. We will include at least 5 hospitals to cover high, medium and low volume centres and get representation across the health delivery service.

### What are the possible benefits and risks of participating?

This is an observational study and no additional risk or benefits to participants are anticipated.

#### Patient and public involvement:

We have conducted a pre-study online survey with the Kidney Cancer UK (KCUK) charity. Our patient representatives for this study have been involved in drafting the study protocol and will represent patient views on the trial management committee.

#### Where is the study run from?

From University College London (UK) and 5 hospitals in the UK

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

From February 2020 to September 2022

#### Who is funding the study?

National Institute for Health Research (NIHR) (UK)

#### Who is the main contact?

Maxine Tran  
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## Contact information

#### Type(s)

Scientific

#### Contact name

Ms Maxine Tran

#### Contact details

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## Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

#### Integrated Research Application System (IRAS)

275481

#### ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

CPMS 45891, IRAS 275481

# Study information

## Scientific Title

Identifying the facilitators and barriers to implementation of tumour biopsy in the diagnostic pathway for small renal masses

## Study objectives

1. What are the patient, public and professional preferences and views in relation to the usefulness of tumour biopsy in the management of small renal masses (SRM)?
2. What is the impact of renal tumour biopsy (RTB) on provision of care, in terms of clinical processes and outcomes?
3. What is the impact of RTB on patient experience, including choice and treatment decision making process?
4. What is the cost and cost-effectiveness of an RTB service?
5. What interventions (professional or organisational) would be required to enable implementation of RTB in the diagnostic pathway of small renal masses?

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 04/08/2020, South Central - Berkshire Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207 104 8056; [berkshire.rec@hra.nhs.uk](mailto:berkshire.rec@hra.nhs.uk)), ref: 20/SC/0244

## Study design

Observational qualitative

## Primary study design

Observational

## Study type(s)

Diagnostic

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

Renal tumour

## Interventions

Each participant could be involved in 1 or all 3 of the different method approaches. There will be no follow-up but participants will be able to contact the study team if they have further questions.

This study will employ an exploratory mixed-methods approach. Potential participants will be firstly invited to partake in individual interviews, from which the key factors that influence decision-making in relation to adopting Renal Tumour Biopsy (RTB) will be extracted. Once such factors are identified, a larger sample of potential participants will be asked to partake in a short questionnaire evaluating the wider prevalence of such factors, and the applicability and preferences for a range of potential solutions. Patients, members of their family, and the public will be invited from all the hospitals, KCUK website, and the UCL Biomedical research PPI network, to take part in focus group discussions hosted locally

Qualitative semi-structured interviews with clinicians, commissioners and patients will be used to capture detailed insights into personal experience and perceptions regarding RTB. Participants will be recruited from 5 hospitals ranging from high to low procedural volume. Patient and public focus groups will explore common trends, perceptions and assumptions while providing diversity among participants. A questionnaire based on the influential facilitators and barriers elicited from the interviews and focus groups will be developed to assess the prevalence of such perceptions from a wider population. Roundtable workshops will include both patients and clinicians to discuss viewpoints and construct intervention strategies. Health economic analysis will be conducted and a decision-analytic model developed to estimate the cost-effectiveness of RTB adoption.

The study team will conduct an exploratory preliminary economic analysis to estimate the cost of RTB intervention adoption in the NHS. To this aim, data will be gathered from available evidence and from expert opinion (e.g. using the interviews with clinicians in the qualitative component of the study). The cost-utility measures will be the incremental cost per unit of change in the Quality Adjusted Life Years (QALY) gained.

A decision-analytic model (Markov model) will be developed to estimate the cost-effectiveness of performing RTB prior to surgery versus current common pathway (no RTB) to diagnose and manage SRMs. The model will estimate the lifetime costs (including active surveillance and robotic/laparoscopic/open surgery costs) and life expectancy of an average patient in both options. The model will be populated using data from published evidence on incidence, probabilities (e.g. false positive or negative tests, complications), NHS reference costs (e.g. the cost of the diagnostic test, surgery, follow up, complications, treatments for cancer), life expectancy and outcomes (e.g. utilities to calculate QALYs). Unit costs will be collected and assessed from the perspective of the NHS and personal social services via standard sources.

## **Intervention Type**

Other

## **Primary outcome(s)**

1. Prevalence of key factors that influence decision-making in relation to adopting Renal Tumour Biopsy (RTB), and the applicability and preferences for a range of potential solutions measured using interviews and questionnaires at a single timepoint. Interviews will be transcribed verbatim and coded using Computer Assisted Qualitative Data Analysis Software (i.e. NVivo). Braun and Clarke's model of thematic analysis with a six-phase approach will be used to generate, review, and define themes within the interview transcripts. Data will be extracted from the online and paper questionnaires and entered into statistical analysis software (i.e. SPSS). The analysis will comprise of both descriptive data (mean and standard deviation/median and interquartile range as appropriate) and inferential statistics, where we will examine whether the prevalence of influences and preference for potential solutions differ between participant groups and according to demographic variables.

## **Key secondary outcome(s)**

There are no secondary outcome measures

## **Completion date**

30/09/2022

## **Eligibility**

**Key inclusion criteria**

1. Healthcare professionals involved in the delivery of Renal Tumour Biopsy (RTB)
2. Patients with current or previous SRM

**Participant type(s)**

Mixed

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

01/09/2020

**Date of final enrolment**

31/03/2022

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre****Broomfield Hospital**

Court Road

Broomfield

Chelmsford

United Kingdom

CM1 7ET

**Study participating centre****The Royal Marsden Hospital**

Downs Road

Sutton

United Kingdom

SM2 5PT

**Study participating centre**  
**Addenbrooke's Hospital**  
Hills Road  
Cambridge  
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CB2 0QQ

**Study participating centre**  
**Lister Hospital**  
Coreys Mill Lane  
Stevenage  
United Kingdom  
SG1 4AB

**Study participating centre**  
**Southmead Hospital**  
Southmead Rd  
Bristol  
United Kingdom  
BS10 5NB

## **Sponsor information**

**Organisation**  
University College London

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

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
NIHR Central Commissioning Facility (CCF); Grant Codes: NIHR200536

**Funder Name**

National Institute for Health Research (NIHR) (UK)

**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

## Results and Publications

**Individual participant data (IPD) sharing plan**

The data sharing plans for the current study are unknown and will be made available at a later date.

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			26/07/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol file</a>	version v1.0	17/02/2020	16/12/2020	No	No