ISRCTN16455338 https://doi.org/10.1186/ISRCTN16455338

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

Submission date
29/09/2020

Recruitment status
No longer recruiting

Registration date
16/12/2020

Overall study status
Completed

Last Edited
22/09/2021

Condition category
Cancer

[ ] 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
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
rf.ifitb@nhs.net

Contact information

Type(s)
Scientific

Contact name
Ms Maxine Tran

Contact details
UCL Department of Surgical Biotechnology
Division of Surgery and Interventional Science
9th Floor Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG
+44 (0)20 7794 0500 ext. 32467
m.tran@ucl.ac.uk

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), 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
United Kingdom
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?
HRA research summary			26/07/2023	No	No
Protocol file	version v1.0	17/02/2020	16/12/2020	No	No