ISRCTN17719284 https://doi.org/10.1186/ISRCTN17719284

PREDICT Kidney clinical feasibility study

Submission date 16/12/2024	**Recruitment status** Recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 19/12/2024	**Overall study status** Ongoing	
Last Edited 23/07/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Kidney cancer is diagnosed in more than 4000 people annually in the UK. If the cancer has not spread outside the kidney, most people affected will have surgery to remove the cancer and part of or the whole of the kidney. They are then followed up for at least 5 years, so that if the cancer returns it is detected quickly.
Follow-up involves having x-rays and CT scans. This can make patients anxious, expose them to radiation and is costly for the healthcare service. It is recommended that doctors should estimate the risk of kidney cancer coming back for each patient, to help them decide how often (and for how long) scans should be carried out. Most surgeons use a risk model called the Leibovich model to estimate the risk of cancer coming back. However, there is a lot of variation in how that is communicated with patients and studies have shown that many patients do not understand their risk or how their follow-up is determined.
Researchers have developed a new online tool, PREDICT Kidney, that enables clinicians to estimate an individual patient's risk of kidney cancer coming back (and the chances of death from other causes) after surgery based on the Leibovich model (or other models in the future) and then communicate that risk to patients using a range of evidence-based images and text. It is hoped that when the tool is used, patients will feel more informed about their risk of the kidney cancer coming back and understand the rationale behind the planned follow-up better. The aim of this study is to test this tool with a small number of patients and clinicians.

Who can participate?
Patients aged 18 years and over from participating hospitals in England and Scotland who have had surgery for kidney cancer

What does the study involve?
Participants will be allocated into two groups based on the timing of their follow-up consultation, 6-weeks after surgery. Those in the first group will have the standard current level of care. This is a face-to-face clinic appointment where they are informed of the estimated risk of the cancer returning (i.e. low, intermediate or high) based on the Leibovich score, and given a follow-up plan based on that risk. For those in the second group, at that face-to-face clinic appointment the clinicians will use the new tool to support the conversation around the risk of the cancer coming back and appropriate follow-up. Using the tool, clinicians will give participants an estimated percentage risk of the cancer returning, again calculated based on the Leibovich score, alongside the corresponding estimated percentage risk of dying from other causes. The

participants will also be given a printout of those estimated risks. We will ask to video- or audio-record some consultations in both groups. Both groups of patients will then be given questionnaires to complete before, immediately after and 3 months after their appointment. The researchers will also speak to a sample of patients in the second group and healthcare professionals to seek feedback regarding the tool. They will use the findings from this study to improve the tool and plan a larger study to test whether using it improves patients' understanding of their risk of recurrence and planned follow-up.

What are the possible benefits and risks of participating?
To take part, participants will need to give up time to arrive 20 minutes early for their appointment and to complete the questionnaires. There are no medical risks in taking part but the questionnaires will include questions about cancer returning in the future and this can potentially cause anxiety.
The main benefit of taking part is an opportunity to help the research team support discussions and decision-making about follow-up care in patients who have been treated for kidney cancer. Participants allocated to the intervention group (the second group) will also receive more detailed information about the chances of their cancer returning.

Where is the study run from?
University of Cambridge and Cambridge University Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2024 to December 2025

Who is funding the study?
1. National Institute for Health and Social Care Research for Patient Benefit (UK)
2. CRUK Major Centre and BRC: Cancer Research UK Cambridge Centre (UK)

Who is the main contact?
Dr Juliet Usher-Smith, jau20@medschl.cam.ac.uk

Contact information

Type(s)
Scientific, Principal Investigator

Contact name
Dr Juliet Usher-Smith

ORCID ID
https://orcid.org/0000-0002-8501-2531

Contact details
Dept of Public Health and Primary Care
University of Cambridge
East Forvie Building
Cambridge
United Kingdom
CB1 0SZ
+44 (0)1223748693
jau20@medschl.cam.ac.uk

Type(s)
Public

Contact name
Mrs Jessica Kitt

ORCID ID
https://orcid.org/0000-0003-0134-5564

Contact details
University of Cambridge
Norman Bleehen Oncology Offices
Addenbrookes Hospital
Hills Road
Cambridge
United Kingdom
CB2 0QQ
+44 (0)1223748693
jk896@cam.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
343656

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 64588, NIHR Central Commissioning Facility (CCF) Grant Code: NIHR205404

Study information

Scientific Title
A feasibility study of incorporating the PREDICT Kidney risk communication tool into clinical care for patients who have undergone surgery for newly diagnosed localised renal cell carcinoma

Acronym
PREDICT kidney feasibility study

Study objectives
This is a feasibility study to assess the feasibility and acceptability of incorporating the PREDICT Kidney online tool into the first post-surgery follow-up appointments for patients with localised renal cell carcinoma and to evaluate participant recruitment, completeness of data collection and estimates of the patient-level outcomes to inform the design of a future trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 23/10/2024, East of England - Cambridge South Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, United Kingdom; +44 (0)207 104 8084; cambridgesouth.rec@hra.nhs.uk), ref: 24/EE/0216

Study design
Prospective feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

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

Health condition(s) or problem(s) studied
Primary localised renal cell cancer of clear cell subtype

Interventions
The researchers will invite adults from participating hospitals in England and Scotland who have had surgery for kidney cancer to take part in the study. Potential participants will be invited to take part after they have had surgery and before their first follow-up consultation. The researchers hope to recruit around 60 patients. Participants will be allocated into two groups based on the timing of their follow-up consultation, 6 weeks after surgery. Those in the first group will have the standard current level of care. This is a face-to-face clinic appointment where they are informed of the estimated risk of the cancer returning (i.e. low, intermediate or high) based on the Leibovich score, and given a follow-up plan based on that risk. For those in the second group, at that face-to-face clinic appointment the clinicians will use the new tool to support the conversation around the risk of the cancer coming back and appropriate follow-up. Using the tool, clinicians will give participants an estimated percentage risk of the cancer returning, again calculated based on the Leibovich score, alongside the corresponding estimated percentage risk of dying from other causes. The participants will also be given a printout of those estimated risks. The researchers will ask to video- or audio-record some consultations in both groups. Both groups of patients will then be given questionnaires to complete before, immediately after and 3 months after their appointment. The researchers will also speak to a sample of patients in the second group and healthcare professionals to seek feedback regarding the tool.

Intervention Type

Other

Phase
Not Specified

Primary outcome measure
The primary aim of this study is to assess the feasibility and acceptability of incorporating the PREDICT Kidney online tool into the first post-surgery follow-up appointments for patients with localised renal cell carcinoma and to evaluate participant recruitment, completeness of data collection and estimates of patient-level outcomes to inform the design of a future trial. As such, the primary outcomes are:
1. Uptake into the study measured by the proportion of eligible patients invited to participate who consent to take part measured at the completion of recruitment
2. Completeness of data collection measured by the proportion of patients who consent to participate in the trial who complete the questionnaires measured at the completion of recruitment
3. The time needed to use the tool and any change in the overall length of consultation measured by the delivery time of the PREDICT Kidney tool during consultation appointments (intervention group only) and the length of consultation appointments (both groups)
4. The acceptability of integrating the tool into clinical care to patients and clinicians assessed in interviews 2-6 weeks post consultation
5. The adherence to the study “best-practice” guide by clinicians and variability between clinicians and sites in the use of the tool measured by clinician adherence to the “best practice” checklist within the consultation
6. Estimates of patient-level clinical outcomes to inform the choice of outcomes for a subsequent trial, including:
6.1. Subjective comprehension of risk of recurrence and follow-up measured using questionnaire items immediately post-consultation
6.2. Objective comprehension of risk of recurrence measured using questionnaire items immediately post consultation and at 3 months post-consultation
6.3. Perceived risk of cancer recurrence measured using questionnaire items immediately post consultation and at 3 months post-consultation
6.4. Risk conviction measured immediately using questionnaire items post-consultation and at 3 months post-consultation
6.5. Satisfaction with the information provided on the risk of recurrence and follow-up measured using questionnaire items immediately post-consultation
6.6. Fear of cancer recurrence measured using questions from the Fear of Cancer Recurrence Inventory short form immediately post consultation and at 3 months post consultation

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/02/2024

Completion date
31/12/2025

Eligibility

Key inclusion criteria

1. Patients treated with surgery for primary localised kidney cancer awaiting their first follow-up appointment after discharge
2. RCC is of clear cell subtype
3. Aged 18 years or over
4. Able to read and write in English
5. Able to understand and sign the written Informed Consent Form

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Patients known to have any condition, which in the opinion of the local principal investigator makes the subject unsuitable for study participation
2. Patients with a known familial syndrome
3. Patients with a second primary kidney cancer

Date of first enrolment
27/01/2025

Date of final enrolment
30/09/2025

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Addenbrookes
Addenbrookes Hospital
Hills Road

Cambridge
United Kingdom
CB2 0QQ

Study participating centre
The Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh
Lothian
United Kingdom
EH4 2XU

Sponsor information

Organisation
Cambridge University Hospitals NHS Foundation Trust

Sponsor details
Cambridge Biomedical Campus, Hills Road
Cambridge
England
United Kingdom
CB2 0QQ
+44 (0)1223 217418
cuh.research@nhs.net

Sponsor type
Hospital/treatment centre

Organisation
University of Cambridge

Sponsor details

University of Cambridge School of Clinical Medicine
Addenbrooke's Hospital
Hills Road
Cambridge
England
United Kingdom
CB2 0SP
+44 (0)1223769291
Cad50@medschl.cam.ac.uk

Sponsor type
University/education

Funder(s)

Funder type
Government

Funder Name
National Institute for Health and Care 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
CRUK Major Centre and BRC: Cancer Research UK Cambridge Centre

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal within 1 year of the end of follow-up

Intention to publish date

01/07/2026

Individual participant data (IPD) sharing plan

The datasets (questionnaire data) generated during and/or analysed during the current study will be stored in a publicly available repository

IPD sharing plan summary

Stored in publicly available repository