

# Is partial removal of the kidney better than removing the whole kidney for patients with intermediate-size kidney tumours?

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<b>Registration date</b> 19/01/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 03/06/2025	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-looking-at-two-different-types-of-surgery-for-kidney-cancer-partial>

### Background and study aims

PARTIAL is a research study looking at two different types of surgery for kidney cancer. Every year, over 13,000 people in the UK have a tumour on their kidney: some of these are kidney cancer, and others turn out not to be cancer. Often, these tumours are identified when they are at the early stages of growth (up to 7cm), and if there is no spread to other parts of the body the two main types of surgery that can be done are the removal of the whole kidney if there is a normal kidney on the other side (radical nephrectomy) and partial removal of the kidney where only part of the kidney (where the tumour is) is removed (partial nephrectomy). Each of these types of surgery has potential benefits and risks, but there is no good evidence for doctors and surgeons working in the NHS about which operation is better. When surgeons remove part of the kidney, there is a higher chance of bleeding, but in the longer term, the person's kidney function may be better. It is also unclear which type of surgery is the best option for patients. The PARTIAL study will compare these two different types of surgery to answer the question of whether a partial removal of the kidney is better than removing the whole kidney for a group of more complex kidney tumours suitable for either approach.

### Who can participate?

Adult patients in the UK with suspected or confirmed stage T1 renal cell carcinoma (a type of kidney cancer), who are suitable to have either operation by keyhole surgery

### What does the study involve?

Adults who consent to participate in PARTIAL will be randomly allocated to one of the two types of surgery mentioned above. We will keep in touch with participants for 24 months to collect information on several things, including how well the kidney(s) are working (through regular blood tests), any complications of surgery and quality of life.

What are the possible benefits and risks of participating?

Both types of surgery are already being used in the NHS to treat patients who need kidney surgery. There are risks associated with all surgical procedures but there should be no additional risk in taking part in the study. Participants may not benefit personally from taking part but, by taking part, will help inform the treatment of future patients who need to have kidney surgery. The results of the PARTIAL study will help doctors, surgeons, patients and health services decision-makers understand whether it is better to remove the whole kidney or part of the kidney.

Where is the study run from?

The Newcastle upon Tyne Hospitals NHS Foundation Trust (UK) and the University of Aberdeen (UK)

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

June 2022 to June 2027

Who is funding the study?

National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA) (UK); Grant Codes: NIHR133561

Who is the main contact?

Diana Johnson, [partial@abdn.ac.uk](mailto:partial@abdn.ac.uk)

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Naeem Soomro

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Principal investigator

### Contact name

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**Type(s)**

Public

**Contact name**

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**Additional identifiers****Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

318662

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

CPMS 54664, IRAS 318662

**Study information**

## Scientific Title

The PARTIAL study: A randomised trial of the clinical and cost-effectiveness of complex PARTIAL versus radical nephrectomy for clinically localised renal cell carcinoma

## Acronym

PARTIAL

## Study objectives

Partial nephrectomy for intermediate-sized 4-7cm (T1b) and small <4cm (T1a) endophytic (deep-seated) tumours result in better renal function by at least 10mls/min/1.72m<sup>2</sup> compared to radical nephrectomy in patients with a normal contralateral kidney.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 12/12/2022, South West - Central Bristol Research Ethics Committee (Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 (0)207 1048029; centralbristol.rec@hra.nhs.uk), ref: 22/SW/0171

## Study design

Randomized interventional study

## Primary study design

Interventional

## Study type(s)

Treatment

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

Renal cancer

## Interventions

Potential participants will be identified through hospital urologist clinics and screening in local and regional specialist multi-disciplinary teams. Adults with suspected or confirmed clinically localised kidney cancer on imaging with a normal functioning kidney on the other side and considered suitable for both minimally invasive (keyhole) radical or partial nephrectomy will be considered. Those with suspected kidney cancer are eligible for inclusion due to the low uptake of biopsy amongst patients (as described in section A6-2). Potential participants being considered for open surgery will be excluded from the study as open surgery has significantly more complications than keyhole surgery and is generally reserved for tumours which are outside the inclusion criteria of the study.

Eligible participants will be given information about the study. Those who are interested in taking part will discuss the surgical options and the study with a member of the clinical team during a face-to-face or virtual consultation. If the participant decides to give their consent, they will be asked to sign a consent form (electronic or hard copy, as per preference) and complete a baseline questionnaire. Participants can complete this at a consultation or at home. If completed at home, this may be supported by a telephone call from the site (if the participant agrees to this contact) and the consent form and baseline questionnaire, if done as hard copy, will be returned through the post.

The local research team will complete a baseline case report form collecting data on age, sex,

ethnicity, height, weight, postcode, medical history, smoking status, kidney function (eGFR - measured by a blood test, the standard of care), tumour size and location (measured on imaging, the standard of care) and biopsy results (only if a biopsy is offered as part of the standard of care and if the participant agrees to biopsy).

Participants will be randomised to either a partial nephrectomy or a radical nephrectomy. If a participant agrees to a biopsy prior to surgery (as part of the standard of care), the participant will be randomised after the biopsy if the surgeon and patient are still in equipoise about the treatment options.

The procedure (radical or partial nephrectomy) is undertaken as per standard care. Blinding is not possible.

The local research team will collect information about the surgical procedure, any intraoperative complications and pathology results from medical records (or in real-time, as applicable).

Clinical follow-up will coincide with routine follow-up for these participants unless indicated otherwise in the text below. Another follow-up is by questionnaires (post, email, or text).

3 months after surgery, the local research team will collect information from the medical records to complete the Comprehensive Complications Index, recording any complications following surgery. The participant's kidney function (eGFR) will be collected from laboratory records. eGFR is measured by blood tests either post-operatively, at hospital outpatient clinics or in primary care (as applicable). The key measurements of eGFR for PARTIAL are within 1 week of surgery and at 1 month after surgery and 6, 12 and 24 months after randomisation. These blood tests are standard of care post-operatively for those with confirmed renal cancer.

Participants who do not have confirmed renal cancer following surgery, these participants will still be followed up in the study but regular kidney function tests may not be part of the standard of care. In such cases, these participants will be invited to attend study-specific follow-ups with the aim of obtaining the kidney function measurement by blood test at the above approximate time points.

Participants will be asked to complete questionnaires by post, email or text (as per participant preference) at 1 week and at 1 and 3 months after surgery and 6, 12, 18 and 24 months post-randomisation to collect information (at the relevant time point) on quality of life, quality of recovery, NHS resource use and participant costs, time and travel and acceptability and to report any complications.

24 months after surgery, the local research team will collect information from the medical records including major adverse cardiovascular events, evidence of cancer recurrence (from routine scans), further treatment and any late complications that have occurred since randomisation.

Outcomes will then be compared between partial nephrectomy and radical nephrectomy. Participants will give consent for longer-term follow-up - to access the medical information on long-term outcomes including cardiovascular events, survival and kidney function and to access tissue from pathology archives for future studies (based on separate funding and relevant approvals).

There is a qualitative sub-study which will identify challenges relating to the design and conduct of the trial, particularly around recruitment.

The first component of this involves analysing anonymised screening logs to support recruitment activity. Audi-recording consultations will be implemented at trial sites. Participants will receive information about this in advance of the consultation and will be asked to give verbal agreement for the recording at the start of their consultation.

The second component of this will involve interviews with (i) site staff and (ii) participants who consented and declined to participate in PARTIAL. Site staff will be emailed an invitation letter and invited to contact the qualitative research team (by email/telephone) if interested in taking part. Potential participants will be provided with information by the local research teams with a reply slip to complete and return to the qualitative researcher if interested in taking part.

Participants who do not return the reply slip will not be contacted further. Participants and site

staff interested in taking part will be telephoned by the qualitative researcher and, if they agree to take part, verbal agreement for the interview will be sought at the beginning of the interview. Interviews will be completed by telephone or online (eg. Microsoft TEAMS). Results will be fed back as anonymised summaries to site staff and the project management group to support improvements in recruitment and retention.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome(s)**

1. Renal function preservation by estimated glomerular filtration rate (eGFR) measured using a blood test and standard procedures at baseline, 1 week and 1 month after surgery and 6, 12 and 24 months after randomisation
2. Surgical complications measured using the Comprehensive Complications Index (CCI) to 3 months after surgery

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

1. Health-related quality of life (HRQoL) measured using the EORTC Core Quality of Life questionnaire (EORTC QLQ-C30) and the 36-Item Short Form Health Survey (SF-36) acute version (1-week recall) participant questionnaires at baseline, 1 week, 1 month and 3 months after surgery and 3, 6, 12, 18 and 24 months after randomisation
2. Cost-effectiveness (quality-adjusted life-year and costs) measured using case note reviews and participant questionnaires at baseline, surgery, 1 week, 1 month and 3 months after surgery and 3, 6, 12, 18 and 24 months after randomisation
3. Quality of recovery capturing length of stay measured using the 15-item Quality of Recovery-15 (QoR-15) scale participant questionnaire at 1 week, 1 month and 3 months after surgery
4. Rates of positive surgical margin rates and retreatment / surgical revision measured by case note review (pathology report) at surgery and 24 months after randomisation
5. Recurrence-free and overall survival including local recurrence measured by case note review at 24 months after randomisation
6. Cardiovascular events (non-fatal heart attack, non-fatal stroke and cardiovascular death) measured by case note review at 24 months after randomisation
7. Progression to chronic kidney disease stages 3, 4, and 5 (added 04/03/2024: including end-stage renal failure) by estimated glomerular filtration rate (eGFR) measured using a blood test and standard procedures at baseline, 1 week and 1 month after surgery and 6, 12 and 24 months after randomisation
7. Operative conversion to radical nephrectomy measured by case note review at surgery
8. Patient acceptability measured using interviews in embedded mixed methods trial process evaluation and participant questionnaire at 3 months after surgery

## **Completion date**

30/06/2027

## **Eligibility**

### **Key inclusion criteria**

1. Adults  $\geq 18$  years
2. Newly diagnosed clinically localised renal cancer (suspected on cross-sectional imaging or histologically confirmed)
3. Local multi-disciplinary review identifying those cases thought to be suitable for both minimally invasive RN or PN; (for minimally invasive we mean laparoscopic or robotic surgery;

cases where open surgery is planned are not eligible)

4. Cross-sectional imaging showing a single tumour, stage T1 (up to 7cm), where there is equipoise in the MDT and willingness to recruit into the trial

5. On imaging, evidence of a radiologically normal contralateral kidney

6. Patients that have been fully counselled of all the available treatment options (including non-surgical approaches, where appropriate)

7. Able and willing to give informed consent to participate and to participate in study procedures

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

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. Solitary functioning kidney

2. Metastatic disease

3. Existing Chronic Kidney Disease (> stage 3b; eGFR< 45)

4. Medically unfit for surgery

5. Congenital renal abnormality which includes fusion, assent and malrotation

6. Suspected or confirmed inherited kidney cancer syndrome

7. Current pregnancy or breastfeeding

8. People without capacity

### **Date of first enrolment**

01/01/2023

### **Date of final enrolment**

30/09/2026

## **Locations**

### **Countries of recruitment**

United Kingdom

England

Scotland

Wales

**Study participating centre**  
**Centre for Healthcare Randomised Trials (CHaRT)**  
Health Sciences Building  
University of Aberdeen  
Foresterhill  
Aberdeen  
United Kingdom  
AB25 2ZD

**Study participating centre**  
**Norfolk & Norwich University Hospital**  
Colney Lane  
Colney  
Norwich  
United Kingdom  
NR4 7UY

**Study participating centre**  
**Churchill Hospital**  
Old Road  
Headington  
Oxford  
United Kingdom  
OX3 7LE

**Study participating centre**  
**Stepping Hill Hospital**  
Poplar Grove  
Hazel Grove  
Stockport  
United Kingdom  
SK2 7JE

**Study participating centre**  
**Leicester General Hospital**  
Gwendolen Road  
Leicester  
United Kingdom  
LE5 4PW

**Study participating centre**  
**Freeman Road Hospital**  
Freeman Road  
High Heaton  
Newcastle upon Tyne  
United Kingdom  
NE7 7DN

**Study participating centre**  
**University Hospital of Wales**  
Heath Park  
Cardiff  
United Kingdom  
CF14 4XW

**Study participating centre**  
**Addenbrookes Hospital**  
Hills Road  
Cambridge  
United Kingdom  
CB2 0QQ

**Study participating centre**  
**Walsgrave Hospital**  
Clifford Bridge Road  
Coventry  
United Kingdom  
CV2 2DX

**Study participating centre**  
**Guys Hospital**  
Great Maze Pond  
London  
United Kingdom  
SE1 9RT

**Study participating centre**  
**Sunderland Royal Hospital**  
Kayll Road

Sunderland  
United Kingdom  
SR4 7TP

**Study participating centre**  
**Royal Wolverhampton Hospital**  
Wolverhampton Road  
Wolverhampton  
United Kingdom  
WV10 0QP

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

**Study participating centre**  
**Royal Devon & Exeter Hospital (wonford)**  
Barrack Road  
Exeter  
United Kingdom  
EX2 5DW

**Study participating centre**  
**Derriford Hospital**  
Derriford Road  
Plymouth  
United Kingdom  
PL6 8DH

**Study participating centre**  
**Gartnavel General Hospital**  
1053 Great Western Road  
Glasgow  
United Kingdom  
G12 0YN

**Study participating centre**  
**Southend University Hospital**  
Prittlewell Chase  
Westcliff-on-sea  
United Kingdom  
SS0 0RY

**Study participating centre**  
**Charing Cross Hospital**  
Fulham Palace Road  
London  
United Kingdom  
W6 8RF

**Study participating centre**  
**Eastbourne District General Hospital**  
Kings Drive  
Eastbourne  
United Kingdom  
BN21 2UD

**Study participating centre**  
**East Kent Hospitals University NHS Foundation Trust**  
Kent & Canterbury Hospital  
Ethelbert Road  
Canterbury  
United Kingdom  
CT1 3NG

**Study participating centre**  
**University Hospitals of Derby and Burton NHS Foundation Trust**  
Royal Derby Hospital  
Uttoxeter Road  
Derby  
United Kingdom  
DE22 3NE

**Study participating centre**  
**Manchester Royal Royal Infirmary**  
Cobbett House

Oxford Road  
Manchester  
United Kingdom  
M13 9WL

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

**Study participating centre**  
**The Royal Marsden Hospital (london)**  
Fulham Road  
London  
United Kingdom  
SW3 6JJ

**Study participating centre**  
**Liverpool University Hospitals NHS Foundation Trust**  
Royal Liverpool University Hospital  
Prescot Street  
Liverpool  
United Kingdom  
L7 8XP

**Study participating centre**  
**Princess Royal Hospital**  
Lewes Road  
Haywards Heath  
United Kingdom  
RH16 4EX

**Study participating centre**  
**Arrowe Park Hospital (site)**  
Arrowe Park Hospital  
Arrowe Park Road

Wirral  
United Kingdom  
CH49 5PE

**Study participating centre**  
**Royal Free London NHS Foundation Trust**  
Royal Free Hospital  
Pond Street  
London  
United Kingdom  
NW3 2QG

**Study participating centre**  
**Royal Hallamshire Hospital**  
Glossop Road  
Sheffield  
United Kingdom  
S10 2JF

**Study participating centre**  
**Pinderfields Hospital**  
Aberford Road  
Wakefield  
United Kingdom  
WF1 4DG

**Study participating centre**  
**Aberdeen Royal Infirmary**  
Foresterhill Road  
Aberdeen  
United Kingdom  
AB25 2ZN

**Study participating centre**  
**St Georges University Hospital Laboratory**  
St. Georges Hospital  
Blackshaw Road  
London  
United Kingdom  
SW17 0QT

**Study participating centre**  
**Russells Hall Hospital**  
Pensnett Road  
Dudley  
United Kingdom  
DY1 2HQ

**Study participating centre**  
**Victoria Hospital**  
Hayfield Road  
Kirkcaldy  
United Kingdom  
KY2 5AH

**Study participating centre**  
**Frimley Park Hospital**  
Portsmouth Road  
Frimley  
Camberley  
United Kingdom  
GU16 7UJ

## **Sponsor information**

**Organisation**  
Newcastle upon Tyne Hospitals NHS Foundation Trust

**ROR**  
<https://ror.org/05p40t847>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Health Technology Assessment Programme

## Alternative Name(s)

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The final trial dataset will be accessible to the trial statistician and health economist for the purpose of trial analysis. The final trial database may also be made available on reasonable request. A request to access the final trial datasets generated during the trial should be directed in the first instance to the chief investigator (Professor Naeem Soomro; n.soomro@nhs.net). The datasets collected in questionnaires at all timepoints, transcripts of process evaluation interviews, and the baseline, surgery, discharge and pathology, 3-month (CCI), eGFR follow-up, 24-month and serious adverse event case report forms for all participants recruited to the trial will be available. The dataset will be available in fully anonymised electronic form, at an individual level and in accordance with participant consent. The data dictionaries, trial protocol, statistical analysis plan, health economics plan, patient information leaflet and template case report forms will also be available on request to facilitate interpretation of data. Questionnaire templates, or parts thereof, may be available pending review of the relevant licensing agreements. Electronic data for the trial will be available within a local repository at the University of Aberdeen and will be retained for a period of at least 5 years after close of trial in accordance with funder, sponsor and local archiving procedures. Applicants will be required to complete a data request form that will be reviewed by a Data Sharing Committee, which includes the chief investigator. Applications will be considered on a case-by-case basis from bona fide researchers. We are obligated to ensure that optimal use is made of the data that are collected for research and we recognise the value of sharing individual-level data. The interests of research participants, researchers and other stakeholders will be considered when considering each application. A fully authorised data sharing agreement will be required prior to the release of data.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes