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

Submission date
16/01/2023

Recruitment status
Recruiting

Registration date
19/01/2023

Overall study status
Ongoing

Last Edited
03/06/2025

Condition category
Cancer

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

Study website
https://w3.abdn.ac.uk/hsru/PARTIAL/Public/Public/index.cshtml

Contact information

Type(s)
Principal Investigator

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Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
318662

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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/1.72m2 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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
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 measure
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

Secondary outcome measures
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

Overall study start date
01/06/2022

Completion date
30/06/2027

Eligibility

Key inclusion criteria
1. Adults >=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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 420; UK Sample Size: 420

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
England

Scotland

United Kingdom

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

Sponsor details
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Gosforth
Newcastle-Upon-Tyne
England
United Kingdom
NE7 7DN
+44 (0)1912825959
tnu-tr.sponsormanagement@nhs.net

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
30/06/2028

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?
HRA research summary			28/06/2023	No	No