ISRCTN18156881 https://doi.org/10.1186/ISRCTN18156881

Nephron-sparing treatment for small renal masses

Submission date
18/02/2019

Recruitment status
No longer recruiting

Registration date
04/03/2019

Overall study status
Completed

Last Edited
30/07/2025

Condition category
Cancer

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

Plain English summary of protocol

Background and study aims
There are 12,500 new cases of kidney cancer every year in the UK and it is predicted that this will rise to 16,000 by 2035. The standard treatment for small kidney cancers is surgical removal of the cancer (partial nephrectomy). However, this is a complex surgery procedure and 1 in 20 patients develop complications such as leakage of urine into the abdomen, bleeding and bowel injury. An alternative treatment option is cryoablation, which involves killing cancer cells by freezing. It has fewer complications, faster recovery and gives equally good cancer control. Currently, cryoablation is mainly offered to elderly patients or patients with significant medical problems. It is not clear if it can also benefit other patients. A clinical trial comparing the two options may answer this question. The researchers want to see if patients are willing to be involved in such a trial by conducting a feasibility study first, which if successful will progress to a full trial. The aim of this study is to see whether patients with small renal cancers will take part in a study to compare cancer treatment by cryoablation with partial nephrectomy.

Who can participate?
Patients aged over 18 with small renal cancers

What does the study involve?
Participants are randomly allocated to be treated with cryotherapy or robot-assisted partial nephrectomy (standard care). Cryotherapy involves freezing of the tumour using percutaneous needles. Robot-assisted partial nephrectomy involves surgery to remove the tumour and leave the rest of the kidney behind. Follow-up for the purposes of this study is 6 months, but standard clinical follow up is at least 5 years.

What are the possible benefits and risks of participating?
It is hoped that cryoablation will help participants experience fewer side effects from treatment than if they had a partial nephrectomy, and, because cryoablation is a less invasive treatment, recovery after surgery will be quicker and participants will be able to go back sooner to their normal day to day life. However, this cannot be guaranteed as it is not known what the outcome of the study will be. This is why this study is being conducted and the information gathered from this study will hopefully help doctors to treat future patients diagnosed with a small renal mass better.

Where is the study run from?
Royal Free NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
April 2019 to June 2023

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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
40911

Study information

Scientific Title
A feasibility study of a cohort embedded randomised controlled trial comparing NEphron-Sparing Treatment (NEST) for small renal masses

Study objectives
Patients with small renal cancers are willing to enter a treatment trial comparing surgery with cryoablation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/02/2019, East Midlands - Derby Research Ethics Committee, The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, Tel: +44 (0)207 104 8109/(0)207 104 8237, Email: NRESCommittee.EastMidlands-Derby@nhs.net, ref: 19/EM/0004

Study design
Randomised; Both; Design type: Treatment, Surgery, Active Monitoring, Cohort 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
Kidney cancer

Interventions
Randomisation will be performed in blocks of 10 participants through the online system 'Sealed Envelope' (www.sealedenvelope.com) to ensure allocation concealment.

1. Cryotherapy (intervention): Involves the freezing of the tumour by using percutaneous needles.
2. Robot-assisted partial nephrectomy (standard care): involves surgery to remove the tumour and leave the rest of the kidney behind.

Follow-up for the purposes of this feasibility trial will be 6 months, but standard clinical follow up will be at least 5 years.

Intervention Type
Procedure/Surgery

Primary outcome measure
Recruitment rate, measured using number of participants recruited per month during the study

Secondary outcome measures
1. Retention rate, measured using randomised participants retained and assessed with valid primary outcome data, measured annually
2. Health-related quality of life measured using EQ5D-5L prior to treatment and 3 months following treatment
3. Complications, blood transfusion, ITU admission and renal replacement requirement rates, measured using clinical records during hospital admission, 30 days post-operative and at 6 months
4. Length of hospital stay, time to return to pre-treatment activities, number of work days lost (in those who work), measured using clinical records and follow-up consultation (clinic or telephone) at 30 days and at 6 months
5. Costs incurred by health technologies, measured using NHS reference costs and also private and societal costs measured using patient completed questionnaire at time of treatment, at 30 days and at 6 months

Overall study start date
29/04/2019

Completion date
17/06/2023

Eligibility

Key inclusion criteria
Inclusion criteria for study cohort:
1. Informed consent
2. Males and females
3. > 18 years of age
4. Diagnosed with renal mass <4 cm in size

Inclusion criteria for randomisation/interventional cohort:
1. Biopsy proven RCC
2. Tumours that are suitable for robot-assisted PN and CO

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 300; UK Sample Size: 300

Total final enrolment
200

Key exclusion criteria
Exclusion criteria for study cohort:
1. Any of the above listed inclusion criteria not met
2. Patient unable to provide or indicate informed consent

Exclusion criteria for randomisation/interventional cohort:
Patients with any concurrent medical/surgical condition or indication, which would mean the SMDT recommends one treatment modality is more suitable than another, such as:
1. Myocardial Infarction in preceding 6/12
2. Pulmonary disease not allowing for prolonged anaesthesia
3. Multiple previous abdominal surgery/interventions, making surgical approach high risk
4. Performance status > = 2
5. Metastatic disease
6. Charlson co-morbidity index > 3
7. Patients with multifocal tumours
8. Patients with suspected or diagnosed with inherited kidney cancer susceptibility syndromes
9. Women that are pregnant or breastfeeding

Date of first enrolment
01/05/2019

Date of final enrolment
17/04/2023

Locations

Countries of recruitment
England

United Kingdom

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

Sponsor information

Organisation
Royal Free London NHS Foundation Trust

Sponsor details
Royal Free Hospital
Pond Street
London
England
United Kingdom
NW3 2QG

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04rtdp853

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: PB-PG-0817-20013

Results and Publications

Publication and dissemination plan
Patient and public involvement
An online survey with Kidney Cancer UK (KCUK) involving ninety-nine patients demonstrated their support and need for such a study. The patient representatives helped draft the study protocol, patient information sheets and consent forms. They will represent patient views on the trial management committee, and will have a central role in the design of the full trial and dissemination of study findings.

The protocol is being submitted for publication. The results will be presented at national and international clinical meetings, published in high impact medical journals and communicated to the kidney cancer community through Kidney Cancer UK (KCUK) patient education days, social media and the KCUK and Royal Free Hospital websites.

Intention to publish date
28/10/2023

Individual participant data (IPD) sharing plan
Anonymised participant level data will be available upon request on a case by case basis, subject to REC approval. Requests can be made to the Chief Investigator. Data will be available not less than 1 year following completion of study and will be available for up to 5 years.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/06/2019	26/06/2020	Yes	No
HRA research summary			28/06/2023	No	No
Results article		09/09/2023	30/07/2025	Yes	No