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CONSERVE study

Submission date 24/05/2012	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 24/05/2012	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 29/03/2022	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
http://cancerhelp.cancerresearchuk.org/trials/a-study-looking-3-different-treatments-for-kidney-cancer-conserve

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT01608165

Secondary identifying numbers
12184

Study information

Scientific Title
A feasibility study for a multicentre randomised controlled trial to compare surgery (partial nephrectomy) with needle ablation techniques (radiofrequency ablation/cryotherapy) for the treatment of people with small renal masses (4cm)

Acronym
CONSERVE

Study objectives
The number of people diagnosed with kidney cancer has doubled over the past 20 years, making it the eight most common cancer in the UK. Most tumours are less than 4cm in size, but over 80% of these are malignant (cancerous) and if left untreated, will slowly grow and spread. Current standard treatment for these small kidney cancers is to remove the diseased part of the kidney in an operation called a partial nephrectomy, but this can be quite a difficult operation. Because of the small tumour size and difficulties with the operation, other treatments have been developed to destroy the tumours. These treatments include radiofrequency ablation, which means that the tumour is destroyed by heat, and cryoablation, which means that the tumour is frozen and destroyed.

Although removing the part of the diseased kidney in an operation is the tried and tested way to treat the kidney cancer, it does have risks and complications, such as bleeding. The other two treatments are less intrusive to the patient, and are less complicated as they do not require such a large operation as having part of the kidney removed, but it is not known if they are as good at destroying all of the tumour, and whether or not patients who have their tumour destroyed with these new methods require further treatment in future.

In this study, we are trying to determine if a large-scale study comparing these treatments is possible which is why this is called a feasibility study. We are also looking at whether patients would be willing to be randomly assigned to a treatment group. The results of this study will then be compared to see how effective each of the treatments were and whether the number of patients who were happy to be randomly assigned to a treatment could be used to determine the number of patients required in a large-scale trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First MREC 09 May 2012 ref: 12/NE/0147

Study design
Randomised interventional treatment trial

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Renal Cancer; Kidney

Interventions
Cryoablation, Participants in this study may be randomised to undergo cryoablation as treatment for their small renal mass; Partial Nephrectomy, Participants in this study may be randomised to undergo a partial nephrectomy as treatment for their small renal mass; Radiofrequency ablation, Participants in this study may be randomised to undergo radiofrequency ablation as treatment for their small renal mass; Follow Up Length: 6 month(s)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
To estimate the number of patients with a renal mass <4cm who agree to trial randomisation measured at over 18 months of recruitment

Secondary outcome measures
1. Evaluation of treatment of tumour by CT scan and biopsy measured at using CT scans at 1, 3 and 6 months after treatment and renal biopsy at 6 months
2. Qualitative interview responses for after treatment for patients who are eligible measured at eight to sixteen weeks after treatment
3. Qualitative interview responses for patients who decline randomisation measured at two to sixteen weeks after recruitment interaction
4. Quality of Life questionnaire reporting differences measured within 14 days of randomisation, and at 3 months and 6 months follow-up

Overall study start date
15/06/2012

Completion date
15/12/2013

Eligibility

Key inclusion criteria
1. Age = 18 years
2. ASA physical status classification system of 1 or 2
3. Radiological confirmation of (>20 Hounsfield Unit) enhancing renal mass (< 4cm) or biopsy proven renal cancer

4. CT abdomen/chest/pelvis with no enlarged nodes or distant metastases
5. Patient has provided written informed consent for participation in the study prior to any study specific procedures
6. Target Gender: Male & Female
7. Lower Age Limit 18 years

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; Description: As this study is open to competitive recruitment, this breakdown of samples size is an estimation

Total final enrolment
74

Key exclusion criteria
1. Coagulopathy
2. Concomitant disease that would render the patient unsuitable for the study
3. Presence of urosepsis
4. Cancer which is completely buried in the kidney
5. More than one small renal cancer mass
6. Previous participation in this study
7. Inability to give informed consent; carer/proxy assent will not be allowed in this study

Date of first enrolment
15/06/2012

Date of final enrolment
15/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

William Leech Building
Newcastle Upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
Leazes Wing
Royal Victoria Infirmary
Queen Victoria Road
Newcastle Upon Tyne
England
United Kingdom
NE1 4LP
+44 (0)191 233 6161
webmaster@rmpd.org.uk

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Charity

Funder Name
Cancer Research UK

Alternative Name(s)
CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Plain English results		27/06/2016	29/03/2022	No	Yes